Overview of the Clinical and Translational Science Awards (CTSAs)

Dr. Lisa Simpson
President and CEO
June 25, 2012
Agenda

→ Overview: The Clinical and Translational Science Awards
  – Funding
  – Structure
  – Focus on Comparative Effectiveness
  – Focus on Community Engagement
→ What do the CTSAs mean for the field of HSR?
→ Questions
Translating New Treatments and Prevention Strategies More Efficiently

Connect Across Translational Continuum

<table>
<thead>
<tr>
<th>CTSA: INDIRECT SUPPORT</th>
<th>CTSA: DIRECT SUPPORT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease</td>
<td>Investigator Training</td>
</tr>
<tr>
<td>Target ID</td>
<td>Technology accelerator(s)/innovation incubator(s)/commercialization facilitation</td>
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<tr>
<td>Assay Dev</td>
<td>Translational genomics technologies</td>
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<tr>
<td>High Thrucut Screen</td>
<td>Large-scale drug discovery program(s)</td>
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<tr>
<td>Probe to Lead</td>
<td>Biobank(s)</td>
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<tr>
<td>Pre-Clinical</td>
<td>High through-put screening capabilities</td>
</tr>
<tr>
<td>POA IND</td>
<td>Large-scale biomarker discovery/validation program(s)</td>
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<tr>
<td>Phase I</td>
<td>cGMP Facilities</td>
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<tr>
<td>Phase II</td>
<td>Clinical Research Data Warehouses (i2b2)</td>
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<tr>
<td>Phase III</td>
<td>Clinical Research Center(s)</td>
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<tr>
<td>FDA Review</td>
<td>Unique study population(s)</td>
</tr>
<tr>
<td>Clinic</td>
<td>Health information exchange</td>
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<tr>
<td>Phase IV</td>
<td>CER infrastructure</td>
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<tr>
<td>Phase V</td>
<td>Electronic Data Capture (REDCap)</td>
</tr>
<tr>
<td>FDA Safety Surveillance</td>
<td>Study Recruitment (ResearchMatch)</td>
</tr>
</tbody>
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Comparative Effectiveness Research
Implementation Science
Community Engagement

Source: CTSA website: https://www.ctsacentral.org
The CTSA Consortium

Source: NIH NCATS website:
http://www.ncats.nih.gov/research/cts/ctsa/about/institutions/map.html
CTSA Recent Accomplishments

In 2011:

- CTSAs supported 7,843 unique grants from 15 federal research institutes and agencies.
- CTSAs supported 5,375 publications communicating scientific findings in diverse research domains and across the entire spectrum of bench-to-bedside-to community translation.
- 1038 trainees and scholars were supported by CTSAs.
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  – Funding
Origin and Funding

- Started by NIH in 2006, led by the National Center for Research Resources (NCRR), a part of the NIH.
- Now based out of NIH’s National Center for Advancing Translational Sciences (NCATS)
- Replaced the General Clinical Research Centers awards (GCRCs)
- In 2012, funding level is at $500 million per year
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  – Funding
  – Structure
Alphabet Soup!

- CTSA
- CCSC
- GCRC
- KFC
- SGC
- T3
- T1
- T2
- T4
- NCRR
- NCATS
Strategic Goals and Key Functions

Source: CTSA website: https://www.ctsacentral.org
CTSA Leadership: Program and Child Health

→ Consortium Steering Committee
  – determine strategic priorities and goals
  – approve new projects
  – ensure adequate progress
  – develop and share policies/ procedures

→ Child Health Oversight Committee
  – identify barriers
  – set priorities for developing collaborative solutions and standard approaches to address the unique challenges in child health research
  – recommend strategies across the CTSA program
Key Function Committees (KFC)

- Administration
- Biostatistics/Epidemiology/Research Design
- Clinical Research Ethics
- Clinical Research Management
- Clinical Services Core
- Communications
- Community Engagement
- Comparative Effectiveness Research
- Education and Career Development
- Evaluation
- Informatics
- Public-Private Partnerships
- Regulatory Knowledge
- Translational
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Mission Statement
The Comparative Effectiveness Research (CER) Key Function Committee builds the field of comparative effectiveness research (CER) and patient-centered outcomes research by creating a learning community across CTSA institutions, spurring the development of methods, expanding training and education, promoting community and public engagement, applying CER findings and sharing successes and lessons learned.

Vision Statement
Through collaborative work products, the Comparative Effectiveness Research (CER) Key Function Committee facilitates the generation and synthesis of evidence about alternative interventions that results in actionable findings for policymakers, clinicians, patients, and purchasers to use in improving the quality and outcomes of patient-centered health care.
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Community Engagement KFC

→ Mission
  – To implement a successful broad plan of community and practice engagement among the CTSA sites by sharing knowledge, expertise and resources.

→ Goal:
  – To effectively engage communities and practices in the translational research process via bidirectional dialogues.
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→ What do the CTSAs mean for the field of HSR?
The Two Translational Blocks in the Clinical Research Continuum

Translational Blocks: T1

- Lack of Willing Participants
- Regulatory Burden
- Fragmented Infrastructure
- Incompatible Databases
- Lack of Qualified Investigators
- Career Disincentives
- Practice Limitations
- High Research Costs
- Lack of Funding

The Two Translational Blocks in the Clinical Research Continuum

Translational Blocks: T2

- Barriers to practice & policy changes
- Regulatory barriers
- Fragmented infrastructure
- Variable policy contexts
  
- Career disincentives
  - Funding differences

1. Basic Biomedical Research
   Translational From Basic Science To Human Studies

2. Clinical Science And Knowledge
   Translation of New Knowledge Into Clinical Practice And Health Decision Making

Improved Health

The Need for Study on T3- T4

Khoury et al. “no more than 3% of research focuses on T2 and beyond”

AcademyHealth Comments on CTSA Program

1. Sustain support for T1-T4 science in CTSAs

2. Support inter-disciplinary approaches along the entire pipeline from innovation, to pilot testing, to rigorous assessment, to replication and spread, to scale-up will need much more attention and investment.
3. Enhance collaboration across sites for infrastructure development, including human capital, data, informatics, and analytic methods.

4. Position the CTSA program to innovate solutions to challenges in the field, e.g., cost of multi-site large studies, training for researchers in multi-disciplinary research.
Questions?

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