The National Center for Advancing Translational Sciences

The Clinical and Translational Science Award Program in the Division of Clinical Innovation

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CTSA PRINCIPAL INVESTIGATOR MEETING
FEBRUARY 3-4, 2015
ACCOMPLISHMENTS IN 2014
Division of Clinical Innovation
Mission

The Division of Clinical Innovation catalyzes clinical and translational science by partnering with stakeholders through support of interdisciplinary research and training to improve individual and public health.
NCATS Division of Clinical Innovation

Strategic Goals

1. Train, develop and cultivate future leaders in translational science

2. Innovate in translational science
   1. Engage patients and communities in every phase of the translational process
   2. Promote the integration of special and underserved populations in translational research across the lifespan
   3. Innovate processes to increase the quality and efficiency of translational research, particularly of multi-site trials
   4. Advance the use of modern informatics in translation

3. Communicate effectively with internal and external audiences using clear, timely, and consistent messages

4. Measure success of the CTSA program through a set of common metrics
Promoting the Future Translational Research Workforce

- Non-traditional skills, such as
  - Regulatory sciences
  - Entrepreneurship

- Experiential learning experience
  - Internships in industry, government or other non-academic organizations

- Team science
  - Multi-disciplinary training

- Making translational research an attractive career path
  - Promotion system
  - Broader range of mentors and training environments
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Engaging Stakeholder and Communities

- Engaging stakeholders across the entire spectrum of translational research
  - Making sure that the research questions matter to patients
  - Ensuring feasible protocols with acceptable burden
  - Promoting stakeholder input into consent language
  - Including patients in implementation and safety oversight
  - Improving dissemination through communication with relevant communities

- Example: NCATS Rare Disease Clinical Research Networks
Including Populations Across the Human Lifespan

• Ensuring that children and the aging benefit from the advances of translational research
  ➢ Point-person for pediatrics and geriatrics
• Promoting the inclusion of special populations or underserved groups
  ➢ Innovation in
    ▪ Methods
    ▪ Technology
    ▪ Policy
  ➢ Community and stakeholder outreach
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Commitment to Local Research

- More than 80% of Hub funding goes to local activities.
- The CTSA program has advanced translational research tools and methods.
- We are adding opportunities for successful local approaches to be more widely disseminated (for example innovation fund projects).
- Building on the existing local strength, we are adding network capacity.
- Together, we can make the CTSA program the go-to place for translational research.
Clinical trials are a critical step in bringing more treatments to patients.

The process is inefficient, lengthy, and in need of innovation.

NIH Clinical Trial Committee found that trials are delayed, of inconsistent quality, often not interpretable and not even published.

FDA leadership notes that NIH funded or academia-based research takes too long and often does not provide data that can be used in evaluating therapeutics.

Strengthening network activities
Role of the CTSA hubs

- The clinical research enterprise needs the transformative leadership of the CTSA PI’s for out of the box thinking.
- Not just “enrolling patients” but transforming the way research is being done.
- The CTSA program must become a strong partner for the NIH IC’s to conduct multi-site research through
  - Increased intellectual contributions to design, protocol, and high quality implementation.
  - A continuously innovating and learning research system.
Evolving the Program to Transform Clinical Translational Science

CTSA Hubs

**TIC:**
Trial Innovation Centers
- Central IRB
- Contracting
- Budgeting
- Other support PRN

**RIC:**
Recruitment Innovation Centers
- Feasibility Assessment
- Recruitment Plan and Implementation

Multi-site Study funded by NIH IC or others

Clinical Lead
Stats/Data Management

No need to re-build trial components each time
CTSA Program initiatives

- Trial Innovation Centers
- Recruitment Innovation Centers
- Innovative Collaborations
- Continuity in opportunities to compete for CTSA Hub funding
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5. **Partner** effectively with NIH and other stakeholders
Steering Committee

- 12 CTSA Principal Investigators
  - 6 new members appointed based on nominations from PIs
  - Annual rotations will allow broad participation
- NIH members: Walter Koroshetz (NINDS), Josie Briggs (NCCIH), Robert Carter (NIAMS), James Doroshow (NCI)
- FDA liaison: Robert Califf
- Public member: Amy Comstock Rick
- The role of the Steering Committee is to
  - Foster communication between PIs and NCATS
  - Guide the Domain Task Forces
  - Provide advice for NCATS to consider in its decision-making
CTSA Communications Structure

- Limited number of groups and voluntary participants
- Outcomes-driven
- Organizationally guided by the SC

CTSA Communications Structure Diagram:
- Council
- NCATS
- Steering Committee
- Lead Team
- Lead Team
- Lead Team
- Lead Team
- Lead Team
- Lead Team
- Workforce Development
- Collaboration Engagement
- Integration Across the Lifespan
- Methods/Processes
- Informatics
- 62 CTSA Hubs
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Evaluation and Metrics

• Need to develop a common set of metrics
• Limited number
  - Collect only what will be analyzed
  - Minimize burden
• Concise framework for regular reporting on the metrics, strategic analysis, and planning
• Strategy and timelines
  - Input from SC, PIs, and external stakeholder group (Working Group of NCATS Council)
  - Goal to launch in 2015
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Partnership with the NIH

- NCATS is actively engaging with the NIH Institutes and Centers at multiple levels
- NIH Clinical Trial Working Group highlighted challenges for NIH-funded trials
  - NCATS is addressing several of these challenges
- NIH Committee on CTSA/IC interactions provided recommendations:
  - Better access to the CTSA program’s intellectual capacity
  - Streamlined research support
  - Increased transparency regarding available resources
  - Standards for training and research across the CTSA network
Partnering with PCORI

• Open line of communication between PCORI/NCATS and PCORNet/CTSA leadership
• Communication groups to coordinate efforts around
  ➢ Subcontracting (Sundeep Khosla and Karl Kieburtz)
  ➢ IRB reliance (Alan Green and CTSA IRB team)
  ➢ Using EHR for research (Nicholas Anderson and Douglas McFadden)
• NCATS is part of NIH groups that coordinate with PCORI
Partnering with FDA

- FDA representatives on Domain Task Forces
- Ongoing interactions with FDA counterparts on opportunities for collaboration in
  - Training
  - Clinical research methods and tools
  - Addressing roadblocks to therapeutics development.
- PK and PM lead working groups in preparation of Joint FDA/NIH Leadership Council in March.
- Rob Califf has agreed to serve on CTSA Steering Committee as FDA liaison.
Take-Home Messages

• The opportunities (and needs) in translational science are huge and systematic, so require *systematic* solutions
  ➢ 21st c. needs cannot be solved with 20th c. structures

• The CTSA program has just begun to transform itself and its programs to meet these opportunities and needs for the benefit of patients.
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