

The CTSA Program at NIH: Opportunities for Advancing Clinical and Translational Research

**IOM Committee to
Review the CTSA Program at NCATS**



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Study Origin and Sponsor

- A December 2011 congressional conference report highlighted the success and additional promise of the CTSA Program.
- The conference report also “urge[d] NIH to support a study by the Institute of Medicine to evaluate the CTSA program and to recommend whether changes to the current mission are needed.”
- In September 2012 the NIH contracted with the IOM to conduct a consensus study to review the CTSA Program.

Statement of Task Highlights

The IOM committee was convened to provide an independent appraisal of and advice on the NIH's CTSA Program as it will be implemented by NCATS.

The committee was specifically asked to

- make recommendations on the appropriateness of the program's current mission and overarching goals
- explore the contributions of the CTSA's in
 - accelerating the development of new therapeutics,
 - facilitating disease-specific research and pediatric research, and
 - enhancing the integration of programs funded by the categorical NIH Institutes and Centers.

Study Timeline

- **October 2012** – First committee meeting
- **November 2012** – Conference call meetings 1 and 2
- **December 2012** – Committee meeting and public workshop
- **January 2013** – Committee meeting and public workshop and conference call meeting 3
- **February 2013** – Conference call meeting 4
- **March 2013** – Final Committee meeting
- **April to May 2013** – National Academies' Report Review
- **June 2013** – Report release

Background and Context

- Recognizing the need to spur clinical and translational research, the NIH established the CTSA Program in 2006.
- From 2006 to 2011, the program was administered by NCRRT. In FY2012, NIH established NCATS, and the CTSA Program became the largest component of NCATS.
- In its first seven years, the CTSA Program grew from 12 initial sites to the current 61.

Background and Context (continued)

- CTSA site budgets range from \$4 million to \$23 million annually, with a total CTSA Program budget of \$461 million in FY2012.
- The CTSA Program does not directly fund or conduct large-scale clinical and translational research, although some individual CTSA do support pilot studies.
- The CTSA Program supports the development and application of shared resources, infrastructure, and innovative technologies for the full spectrum of clinical and translational research.

Changing Research Ecosystem

- Enhanced collaborations
- Emerging data and technology
- Streamlined IRB review processes and enhanced patient protections
- Broader research participant recruitment
- Development of a dynamic research workforce

Overarching Study Conclusions

- The CTSA Program has been successful in establishing CTSAAs as **academic focal points** for clinical and translational research and has begun to build a **national network** that will need to be fully integrated and collaborative to catalyze progress further.
- The CTSA Program is contributing significantly to the advancement of clinical and translational research and is therefore a **worthwhile investment** that would **benefit from a variety of revisions** to make it more efficient and effective.

Key Opportunities for Action

- Adopt and sustain more active program leadership
- Engage in additional substantive and productive collaborations
- Develop and widely disseminate innovative research resources more broadly
- Build on initial successes in training and education, community engagement, and child health research

Recommendation 1

Strengthen NCATS leadership of the CTSA Program

NCATS should strengthen its leadership of the CTSA Program to advance innovative and transformative efforts in clinical and translational research. As it implements CTSA 2.0, NCATS should:

- Increase active involvement in the CTSA cooperative agreements and the CTSA Consortium;
- Conduct a strategic planning process to set measurable goals and objectives that address the full spectrum of clinical and translational research;
- Ensure that the CTSA Program as a whole actively supports the full spectrum of clinical and translational research while encouraging flexibility for each institution to build on its unique strengths;

Recommendation 1 (continued)

Strengthen NCATS leadership of the CTSA Program

As it implements CTSA 2.0, NCATS should:

- Form strategic partnerships with NIH institutes and centers and with other research networks and industry;
- Establish an innovations fund through a set-aside mechanism that would be used for collaborative pilot studies and other initiatives;
- Evaluate the program as a whole to identify gaps, weaknesses, and opportunities and create mechanisms to address them; and
- Distill and widely disseminate best practices and lessons learned by the CTSA Program and work to communicate its value and accomplishments and seek opportunities for further efforts and collaborations.

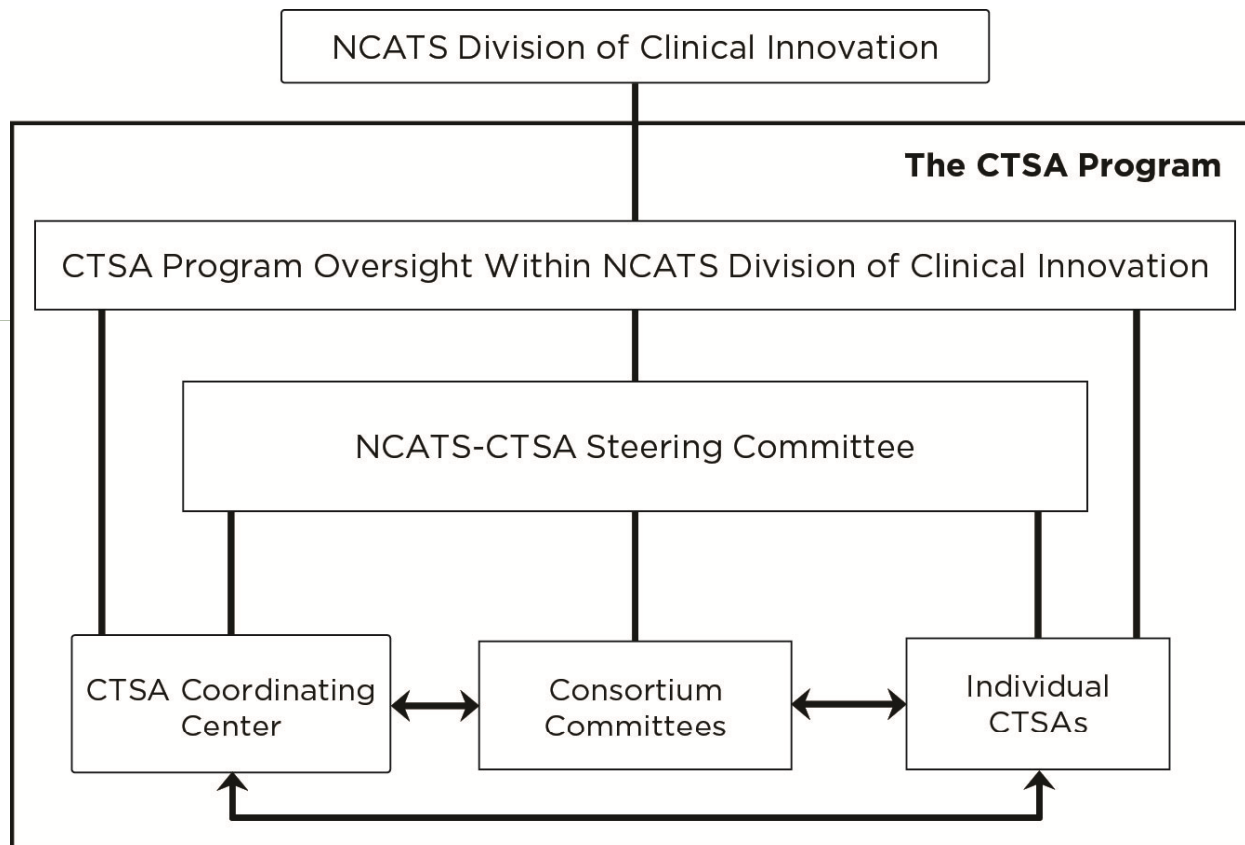
Recommendation 2

Reconfigure and streamline the CTSA Consortium

NCATS should reconfigure and streamline the structure of the CTSA Program by establishing a new multi-stakeholder NCATS-CTSA Steering Committee that would:

- Be chaired by a member of NCATS leadership team and have a CTSA principal investigator as vice-chair, and
- Provide direction to the CTSA Coordinating Center in developing and promoting the use of available shared resources.

Proposed Revised Structure



Recommendation 3

Build on the strengths of individual CTSAs across the spectrum of clinical and translational research

Individual CTSAs, with the leadership of NCATS, should emphasize their particular strengths in advancing the program's broad mission and goals. In doing so, CTSAs should:

- Drive innovation and collaboration in methodologies, processes, tools, and resources across the spectrum of clinical and translational research;
- Emphasize interdisciplinary team-based approaches in training, education, and research;

Recommendation 3 (continued)

Build on the strengths of individual CTSA's across the spectrum of clinical and translational research

In doing so, CTSA's should:

- Involve patients, family members, health care providers, and other community partners in all phases of the work of the CTSA;
- Strengthen collaborations across the schools and disciplines in their home institutions;
- Build partnerships with industry, other research networks, community groups, and other stakeholders; and
- Communicate the resources available through the CTSA Program.

Recommendation 4

Formalize and standardize evaluation processes for individual CTSA and the CTSA Program

The evaluations should use clear, consistent, and innovative metrics that align with the program's mission and goals and that go beyond standard academic benchmarks of publications and number of grant awards to assess the CTSA Program and the individual CTSA.

Recommendation 5

Advance innovation in education and training programs

The CTSA Program should provide training, mentoring, and education as essential core elements. To better prepare the next generation of a diverse clinical and translational science workforce, the CTSA Program should:

- Emphasize innovative education and training models and methodologies, which include a focus on team science, leadership, community engagement, and entrepreneurship;

Recommendation 5 (continued)

Advance innovation in education and training programs

The CTSA Program should:

- Disseminate high-quality online offerings for essential core courses;
- Champion the reshaping of career development pathways for researchers involved in the conduct of clinical and translational science; and
- Ensure flexible and personalized training experiences that offer optional advanced degrees.

Recommendation 6

Ensure community engagement in all phases of research

NCATS and the CTSA Program should ensure that patients, family members, health care providers, clinical researchers, and other community stakeholders are involved across the continuum of clinical and translational research. NCATS and the CTSA Program should:

- Define community engagement broadly and use this definition consistently in RFAs and communications about the CTSA Program;
- Ensure active and substantive community participation in priority setting and decision making across all phases of clinical and translational research and in the leadership and governance of the CTSA Program;

Recommendation 6 (continued)

Ensure community engagement in all phases of research

NCATS and the CTSA Program should:

- Define and clearly communicate goals and expectations for community engagement at the individual CTSA level and across the program and ensure the broad dissemination of best practices in community engagement; and
- Explore opportunities and incentives to engage a more diverse community.

Recommendation 7

Strengthen clinical and translational research relevant to child health

NCATS should collaborate with CC-CHOC to strengthen clinical and translational research relevant to child health through efforts to:

- Identify and designate CTSAAs with expertise in child health research as leaders in advancing clinical and translational research relevant to child health and as coordinators for CTSA programwide efforts and other collaborative efforts in this research; and

Recommendation 7 (continued)

Strengthen clinical and translational research relevant to child health

NCATS should collaborate with CC-CHOC through efforts to:

- Promote and increase community engagement specific to child health by:
 - Raising awareness of the opportunities for children and families to participate in research efforts with clear information conveyed on the risks and potential benefits; and
 - Involving parents, patients, and family members more fully at all stages of the research process, including identifying priorities and setting research agendas.

Opportunities for Action

- ***Adopt and sustain active program leadership***—NCATS should increase its leadership presence, consistent with the cooperative agreement model. A centralized leadership model that includes participation by NCATS, leaders of the CTSA, community partners, and other stakeholders will increase program efficiency, enable mechanisms for accountability, and provide needed direction to develop and nurture substantive partnerships.
- ***Engage in substantive and productive collaborations***—The CTSA Program needs to capitalize on the collaborations developed within and among individual CTSA and continue to forge true partnerships with other NIH institutes and centers and with entities external to the program, including patient groups, communities, health care providers, industry, and regulatory organizations.

Opportunities for Action (continued)

- ***Develop and widely disseminate innovative research resources***—Fully developing the role of the CTSA Program as a facilitator and accelerator of clinical and translational research will require enhanced efforts to engage and support researchers and stakeholders as they develop, refine, disseminate, and implement research and health informatics tools, methodologies, policies, and other resources.
- ***Build on initial successes in training and education, community engagement, and child health research***—The CTSA Program needs to continue its efforts in each of these areas. A robust and diverse workforce that is well trained is critically important. Ensuring an emphasis on community involvement will bring a range of perspectives and innovations along with increased public support. Program efforts can also help overcome the paucity of research specific to child health.

Thank You!

- Questions? Email:
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- Free PDFs of the report are available :
www.iom.edu/CTSAreview

