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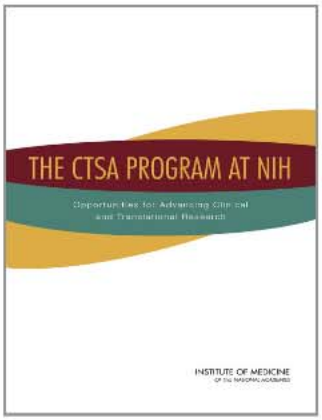
The CTSA Program at NIH

Opportunities for Advancing Clinical and Translational Research



The past half century of biomedical and health research has led to significant improvements in individual and public health. However, it often takes many years before the benefits of research reach individual patients and communities due to the challenges of translating scientific findings into clinical and community practice.

Created in 2006, and currently funded by the National Institutes of Health's (NIH) National Center for Advancing Translational Sciences (NCATS), the Clinical and Translational Science Awards (CTSA) Program aims to facilitate and accelerate the translation of laboratory discoveries into new and better preventive and treatment solutions to improve human health.

At the request of the NIH, the Institute of Medicine (IOM) convened a consensus committee to review the mission and strategic goals of the CTSA Program. The committee's report, *The CTSA Program at NIH: Opportunities for Advancing Clinical and Translational Research*, offers key opportunities for action and recommendations to guide the program and ensure future success.

The Clinical and Translational Science Awards (CTSA) Program aims to facilitate and accelerate the translation of laboratory discoveries into new and better preventive and treatment solutions to improve human health.

Leading the CTSA Program Into the Future

The CTSA Program was developed to provide a wide array of training and research support tools and infrastructure to researchers, research networks, NIH institutes and centers, community stakeholders, health care providers, industry partners, government research agencies, and others to advance clinical and translational science.

Since its inception, the CTSA Program has grown from 12 sites to 61 sites at academic health centers and other institutions across the United States.

For the past seven years, the efforts have focused primarily on developing academic homes for clinical and translational research at individual CTSA sites. The challenge for the next phase of the CTSA Program will be to establish a more integrated and collaborative national network that will further catalyze the development of new diagnostics, therapeutics, and preventive interventions while driving innovation in clinical and translational research methods, processes, tools, and resources and leveraging the ever-expanding capabilities of health informatics tools and other research technologies.

To date, the program has been primarily self-governed by a complex CTSA Consortium—guided by three leadership committees—that oversees numerous committees and subcommittees, which have relied on the energy and efforts of individual CTSAs and their principal investigators (PIs), researchers, and staff. While this grassroots approach has encouraged creativity and innovation, the IOM committee recommends a more centralized leadership approach to guide the next phase of the program. The committee urges NCATS to take a stronger leadership role in the direction and oversight of the CTSA Program and to work with the PIs and researchers to reconfigure and streamline the current structure and to establish a single NCATS-CTSA Steering Committee.

The IOM committee also finds that as the program evolves, NCATS should engage in a strategic planning process in collaboration with the CTSAs to update the CTSA mission and adopt a single set of measurable strategic goals. A revised mission should reflect the program's overarching purpose.

Clearly defined, measurable goals are also needed and will provide the program with a basis for evaluation, reporting, and accountability for the individual CTSAs and the overall program. The committee notes that an updated mission statement and set of strategic goals will also ensure an increased understanding of the program and provide the groundwork for communicating its value.

Engaging in Beneficial Collaborations

A primary function of the CTSA Program is to initiate and foster collaborations across and among researchers and research networks. Now that the program is well established, it must work to further engage in strategic partnerships with a range of public and private entities and stakeholders including other NIH institutes and centers, patient groups, community organizations, private foundations, health care providers, industry, and regulatory bodies in all phases of research.

The committee recommends that CTSA Program establish an innovations fund to promote collaborative pilot studies and other innovative initiatives. The activities supported through

Overview of Recommendations

The next steps for the CTSA Program and opportunities for advancing clinical and translational research are:

- **Strengthen NCATS leadership** of the CTSA Program
- **Reconfigure and streamline** the CTSA Consortium
- **Build on the strengths of individual CTSAs** across the spectrum of clinical and translational research
- **Formalize and standardize evaluation processes** for individual CTSAs and the CTSA Program
- **Advance innovation** in education and training programs
- **Ensure community engagement** in all phases of research
- **Strengthen clinical and translational research** relevant to child health

The IOM committee finds that the CTSA Program is contributing significantly to advancing clinical and translational research, and would benefit from a number of revisions to make the program more efficient and effective and to ensure its future success.

this fund should engage a combination of CTSA institutions and a variety of possible entities and stakeholders, such as those listed above.

One of the challenges ahead will be to capitalize on the efforts of individual CTSAs. Although the program as a whole does not focus on specific diseases, individual sites facilitate research on specific conditions and have established themselves as research leaders. Under the NCATS leadership, the committee recommends a focused effort to continue to build on the work of the CTSAs to emphasize their particular strengths while developing collaborations with other research networks, industry, and community stakeholders to expand the program's capacity.

Building on Initial Success in Education

Developing and retaining diverse and well-trained researchers is key to sustaining a vibrant clinical and translational research workforce, and has been a priority for the CTSA Program. The program must continue to emphasize innovative training, mentoring, and education to better prepare the next generation of researchers.

The committee urges increased flexibility and the implementation of best practices in training and education to attract and retain scholars and trainees. The CTSAs should also create new benchmarks that place value on team-based science, leadership, community engagement, and entrepreneurship.

Engaging the Community

Community engagement is critical in all phases of clinical and translational research from basic research to clinical practice and community and public health research. Community stakeholders can help with efforts to identify health needs and priorities, provide critical input and data, and help promote successful enrollment and retention of participants in health studies. The IOM committee concludes that these partnerships with patients, family members, health care providers, and other community stakeholders need to be preserved, nurtured, and expanded. Because involving community in all of the stages of research may be new to many researchers, NCATS and the CTSA Program must guide this effort and provide clear goals and expectations.

Focus on Child Health

The committee also recommends a continued, coordinated effort to further advance clinical and translational research relevant to child health, an area where little is known about the safety and efficacy of medications, devices, and preventive measures. The current CTSA Consortium Child Health Oversight Committee has made strides in this area, and should work with NCATS to identify a small number of CTSAs with established expertise and outstanding efforts in child health research. These CTSAs should be designated as leaders in this area, collaborating with other CTSAs to expand their efforts.

Furthermore, efforts should continue to promote and increase community engagement specific to child health, and raise awareness of opportunities for children and families to participate in research efforts, clearly conveying all information on the risks and potential benefits.

Conclusion

The IOM committee finds that the CTSA Program is contributing significantly to advancing clinical and translational research, and would benefit from a number of revisions to make the program more efficient and effective and to ensure its future success.

The committee's recommendations for updating the leadership structure and the program's mission and goals are critical to moving the program into its next phase. The necessary changes outlined by the IOM committee, if enacted, would help establish the CTSA Program as the national leader for advancing innovative and transformative clinical and translational research to improve human health.

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