

Clinical and Translational Science

Speeding the translation of medical discovery into enhanced patient care.

BY VICTORIA L. CONTIE

Translating basic discoveries into improved medical care is a cornerstone of research funded by the National Institutes of Health (NIH). Yet scientists who conduct clinical and translational studies face multiple and complex challenges. Technological advances and increased regulatory demands have boosted the complexity and costs of clinical research, creating an increased need for expensive resources like bioinformatics, specialized research training, and staffing for patient recruitment and regulatory compliance. In addition, many physicians who conduct clinical and translational research are strained by dramatic increases in clinical-service demands and declining financial margins, which tend to divert time and attention away from health-related research. As a result, many institutions have difficulties recruiting and retaining a sufficient number of clinical and translational researchers.

To address these problems and accelerate the translation of basic discoveries into improved therapies and clinical practice, NIH in October 2005 launched a new program of institutional Clinical and Translational Science Awards (CTSAs). Through these awards, academic health centers across the country will create individualized academic “homes” for clinical and translational science. “The CTSA Program is designed to spur what will be a fundamental transformation of clinical and translational research in the United States,” says NIH Director Elias A. Zerhouni, M.D. “Our goal is to make sure that new treatments and insights into disease can be captured more efficiently and delivered more quickly to patients.”

The CTSAs, administered by NCRR on behalf of the NIH



■ **The new Clinical and Translational Science Awards are designed to improve patient care by more rapidly bringing new treatments and discoveries to the clinic.**

Roadmap for Medical Research, encourage institutions to propose new approaches to clinical and translational research,

including new organizational models and training programs at graduate and post-graduate levels. The grants also will foster original research to develop clinical research methodologies in areas such as informatics, laboratory methods, technology, and community-based research.

LISTENING TO THE SCIENTIFIC COMMUNITY

Like other NIH Roadmap initiatives, the CTSA addresses issues that are critical to the missions of all NIH components but are beyond the scope of any single NIH institute or center. The NIH Roadmap—launched in 2003 and created in consultation with hundreds of biomedical scientists—identified three fundamental, cross-cutting research themes that could have a significant impact on human health: new pathways to discovery, research teams of the future, and re-engineering the clinical research enterprise.

The latter served as the impetus for the CTSA Program. In ongoing forums and consultations, researchers and administrators described a need to transform clinical and translational science by creating a distinct discipline and an academic home at research institutions across the country.

In May 2005, an NIH-sponsored meeting brought together more than 300 members of the biomedical research community, who shared information about the frustrations and obstacles they encountered, as well as their optimism about the promise of translating basic discoveries into improved medical care. Participants generally agreed that a significant change was needed to enhance clinical and translational science. According to many attendees, institutional and programmatic boundaries had created fragmented research efforts, training programs, and resources that would be more effective if integrated.

at the May 2005 meeting. “Every place is different, so it’s beneficial for institutions to have the flexibility to develop an organizational structure that’s appropriate to their situation,” Swain says.

The TSAs were designed to support the full spectrum of clinical and translational science. Clinical research, as defined by the CTSA Program, includes studies and trials that involve human subjects. Translational research, however, has two key components. The first is the process of applying discoveries made in the laboratory, testing them in animals, and developing trials and studies for humans.



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“The lack of centralized infrastructure has been a huge barrier to conducting clinical and translational research, which often requires expensive processes, facilities, and equipment,” says Richard Rudick, a participant at the May 2005 meeting. Rudick is director of the Mellen Center for Multiple Sclerosis and chairman of the Division of Clinical Research at the Cleveland Clinic. “Another factor is that clinical and translational research requires a team approach, with multiple disciplines participating in the research endeavor. We have not had effective mechanisms for breaking down barriers between basic and clinical sciences to develop such research teams.”

Comments such as these—gathered through multiple consultations with researchers and academic leaders—led NIH to launch the CTSA Program. “The development of the TSAs truly came from listening to the research community,” says NCRR Acting Director Barbara Alving. “We attempted to bring flexibility to the program by providing opportunities for institutions to design their own programs and develop a center, department, or institute of clinical and translational science.”

This flexibility will be critical, says Judith Swain, director of the College of Integrated Life Sciences at the University of California, San Diego. She was among the many investigators who provided input

The second concerns research aimed at enhancing the adoption of best treatment practices into the medical community.

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FORGING PARTNERSHIPS

As one aspect of working together, the TSAs will create two-way synergies with local and regional communities, including the general population, community-based groups, and health-care providers. In one sense, the new academic homes will broaden the scope of their studies by collaborating with local communities. “An exciting aspect of the CTSA Program is its acknowledgment that academic health centers need to develop pipelines and partnerships with communities that reflect a diverse populace,” says Gary Gibbons, director of the Cardiovascular Research Institute at Morehouse School of Medicine and a participant at the May 2005 meeting. “The CTSA Program recognizes that the medical school campus alone is not sufficient for conducting effective clinical and translational research. There must be links to



■ NIH Director Elias Zerhouni announced the creation of the new CTSA Program in October 2005. Developed with extensive input from the biomedical community, the program will create academic “homes” for clinical and translational science.



■ **Biomedical informatics and computer-related technologies enhance the sharing of data across disciplines and across institutions, thus bringing diverse expertise and knowledge to bear on health-related problems.**

communities to ensure that diverse populations, and clinical practitioners within those populations, are a part of addressing important health-related questions.”

In return for the community’s participation, the CTSAs will help to deliver improved medical care to the entire population. “In its broadest definition, translational research includes bringing important discoveries back to the communities by disseminating new technologies and new advances into clinical practice,” according to Gibbons.

Partnerships with foundations and industry also will be crucial to moving discoveries to the clinic. “The CTSAs provide a platform for integrating the interests and the resources of academic health centers, foundations, industrial partners, and communities,” Gibbons adds. “The flexibility of the program creates an open door for these kinds of partnerships, allowing us to look for opportunities where we can leverage resources and have a shared set of objectives that complements NIH’s mission of public health delivery.”

BIOMEDICAL INFORMATICS

Information technologies and biomedical informatics also create new opportunities for forging partnerships by enabling the sharing of data across disciplines and across institutions. “We absolutely need innovation and new approaches for applying information technologies to the research process,” Rudick says. “The challenge is, how do we deal with the massive amount of information that comes from gene sequencing, gene expression, proteomic data, and metabolomics on the one hand, and con-

nect that to data from a particular patient?” In addition, issues related to workflow, usability, and interoperability with collaborating organizations must be addressed, along with the need for ensuring the privacy and confidentiality of human subjects.

The CTSA Program will support the development of such innovations at the institutional level and also will create a nationwide forum in which biomedical informatics directors from all CTSAs will collaborate to develop standards, best practices, and solutions to informatics-related problems.

A LOOK TO THE FUTURE

A key component of each CTSA will be the creation of one or more graduate degree-granting and postgraduate programs in clinical and translational science, which will provide an enriched environment for educating and retaining the next generation of clinical and translational researchers. Through the CTSA Program, investigators will be trained in diverse disciplines such as pediatrics, surgery, dentistry, nursing, and pharmacology. Institutions will have the freedom to create educational programs that best fit their organizational structures and institutional strengths.

“Previous attempts to address the problem through specific grants that fund clinical research training have fallen short, because they were all individual pieces,” says Swain. “The CTSA Program is transforming, because it puts the training pieces together within a cohesive and overarching structure, an academic home.”

NCRR’s Hayward agrees that the creation of well-integrated homes for clinical and translational science will ultimately transform clinical research and medical care. “With the implementation and awarding of CTSAs,” Hayward says, “we expect to see clinical and translational research develop as a distinct discipline. We expect to see new opportunities appear. And we want to see, above all, support for the interdisciplinary teams who will conduct the clinical and translational research of the future.” ■

TO LEARN MORE:

- NIH plans to award four to seven CTSAs in fiscal year 2006, for a total of approximately \$30 million. In addition, a one-time solicitation for CTSA planning grants will give institutions more time to prepare a CTSA application in the future. Approximately 50 planning grants, totaling about \$11.5 million, are expected to be awarded this year. The initial round of CTSA applications are due to NIH by March 27, 2006.
- NIH expects to increase the number of awards annually and to have 60 CTSAs in place by 2012. Funding for the CTSAs will come from the redirection of existing resources, including funds from the NIH Roadmap budget and from existing clinical and translational programs.
- For more information about the CTSA Program, visit the CTSA Web site at www.ncrr.nih.gov/clinicaldiscipline.asp.