

Questions and Answers about the NIH Clinical and Translational Science Award (CTSA) Consortium

Change in Approach

Why are changes necessary? What is the problem that the new awards are trying to address?

NIH recognizes, based on interactions with professional organizations, deans, clinical researchers, that bold new approaches are needed to speed the translation of scientific discoveries into treatments and cures for the 21st Century.

These groups have identified obstacles with the current approach to conducting clinical research that include:

- Fragmented training programs
- Difficulty recruiting and retaining clinical and translational researchers
- Increasing regulatory burden and increasing overhead costs
- Inadequate informatics

To address these and other concerns raised by the research community, the NIH has funded facilities, resources - such as General Clinical Research Centers, grants for individual or institutional training and mentoring, and has provided support for disease-specific centers, clinical trial networks, and training of generations of translational scientists. However, concerns have persisted in the research community that clinical and translational research needs greater attention. The approach of the new CTSA is designed to address these problems. With this more cohesive, targeted approach, new prevention strategies and treatments will be developed, tested, and brought into medical practice more rapidly.

Funding

Will the emphasis on clinical and translational science distract from NIH's funding of basic research?

We are taking great care at NCRR to preserve the investigator-initiated research support pool in these times of constrained budgets. Since the funding for the CTSA is being derived from existing clinical research programs and the NIH Roadmap, no funds are being transferred away from basic research.

How is NIH funding this new program in FY 2006?

The CTSA program will be funded by a combination of NCRR appropriated funds and funds from the NIH Roadmap for Medical Research. The FY 2006 CTSA/GCRC program level is \$363 million. NCRR will provide \$302 million, which includes K30 training grants subsumed within the CTSA and K12 and T32 training program grants that are linked with the CTSA program. The balance, \$61 million, will be provided by the NIH Roadmap for Medical Research, and includes funds from existing Roadmap training programs that will be linked with the CTSA program.

What will happen if Roadmap funding is not available in future years?

The sustainability of the Clinical and Translational Science Award program is not contingent upon the availability of future Roadmap funding. The future depends on the ability of the CTSA program to demonstrate its value and importance, which will greatly influence continued support from Congress and from NCRR.

What is the breakdown between GCRC and CTSA funding in FY 2006? And in FY 2007?

In FY 2006, GCRC funding will total \$243 million, CTSA funding will total approximately \$108 million, and the CTSA planning grants will total \$11.8 million for a first year program total of \$363 million. It is estimated that in FY 2007, the total funds available for the new CTSA awards will be approximately \$38 million and that up to 8 awards may be made. The size of these awards, and therefore the amount that will be spent through CTSA and GCRCs, will depend on the various programs that are consolidated into the CTSA program.

You had expected to fund a total of 79 GCRCs and CSA in Fiscal Year (FY) 2006. You have not been able to meet this combined total. Why?

In FY 2006, 71 GCRCs/CSAs will be funded—8 less than the target of 79. Four GCRCs were terminated following peer-review critique, which reduces the number of GCRCs/CSAs funded to 75. In addition, 16 GCRCs will be subsumed within the 12 CSAs being awarded—three institutions have multiple GCRCs being subsumed within the CSAs—which reduces the number of GCRCs/CSAs being funded to 71.

How many GCRCs have been subsumed into the CTSA program in this round of awards?

Of the 12 CSAs, 9 each subsumed one GCRC. Two CSAs (University of Pittsburgh and University of Pennsylvania) each subsumed 2 GCRCs and one CSA (University of San Francisco) subsumed 3 GCRCs.

What is the total number of CSAs to be funded in the future?

NIH expects to increase the number of awards annually so that by 2012, 60 CSAs will receive a total of approximately \$500 million per year.

In what ways did the successful institutions show commitment to the CTSA program?

Institutional commitment was shown in many ways. Some indicated creating additional space, others assured more protected time for researchers. These examples reflect the various ways institutions are contributing towards creating academic homes for clinical and translational research.

Why are the grants only funded in the first year for 9 months vs 12 months, the traditional award period?

Large programs, such as CTSAAs, are complicated to administer and their funding needs to be distanced from the end of the financial year. NCCR will therefore provide 9 months funding in FY 2006 so that the renewal dates fall on July 1, allowing time for the Annual Reports to be examined before the next year's funding level is determined.

Review and Selection of Awardees

Why were these institutions selected over others?

According to the results from the two-tiered NIH peer review process, their applications were considered the strongest and most responsive to the RFA among those that applied. For some specifics about each of these institutions that describe some of their unique strengths and plans for building an academic home for clinical and translational science, please visit the CTSA directory at http://www.ncrr.nih.gov/ncrrprog/roadmap/CTSA_9-2006.asp.

How were the CTSA selections made?

The applications for these awards underwent two sequential levels of review, which is the standard process for awarding grants at the NIH. The first level involved convening panels of experts from diverse scientific disciplines to evaluate the scientific and technical merit of the grant applications. The second level of review is by the NCCR Advisory Council.

The very broad range of CTSA activity meant that NIH needed to find a corresponding broad range of expertise in the CTSA peer reviewers. For the recruitment of the reviewers, we sought input from across NIH, including the CTSA project team who we brought together to ensure all of NIH interests were represented. In addition, we asked for input from NIH-supported minority serving institutions and from sectors such as public health, nursing, and dental.

All reviewers were vetted for conflict of interest, expertise, and demographics. These experts were selected from across the research community for their expertise and knowledge reviewed and rated the applications.

The scores and evaluations from this process then were reviewed by the National Advisory Research Resources Council, an advisory group to the National Center for Research Resources. These individuals served as the second level of review. The membership includes leaders in scientific disciplines related to the activities of NCCR—including clinical and translational science, as well as members of the general public who are leaders in the fields of public health policies, law, economics, and management. They reviewed and provided concurrence with the reviews of the initial review groups.

Pediatrics

The GCRC program included a particular emphasis on pediatrics. Has pediatrics been given sufficient attention in the CTSA program?

Valuable discussions have taken place with leaders of the pediatric research community to ensure that pediatric clinical research infrastructure would be emphasized in the CTSA program. The first competition for CTSAAs saw applications from institutions with strong pediatric research traditions. Of those that were funded, pediatric research will remain a strong emphasis under the new CTSA program.

Pediatric research at CTSAAs will be monitored closely by the Pediatric Research Steering Committee that NIH will establish. This will be an important opportunity for pediatric research to benefit from the wider range of infrastructure support available through a CTSA.

NIH Management and Evaluation of CTSA Program

How will you ensure proper management and oversight of the CTSAAs?

We have given careful thought to management of the CTSA Program and have developed strategies for effective NIH management of the program as well as strategies for effective governance of the National CTSA consortium. These will be developed further with the awardees.

Pace of Transformation

Why have you funded 12 CTSAAs instead of 7 as planned?

Many of the applications we received were very strong and did so well during the peer review process that we felt it was appropriate to fund more of these institutions since they clearly demonstrated an understanding of the CTSA vision and specific plans to achieve the CTSA goals.

Part of the trans-NIH CTSA Project Team includes Evaluation and Project Management subcommittees that will closely monitor the progress and impact of these institutions to ensure the objectives of the program are achieved. A program, with such broad far-reaching and transformative goals as this one, needs 4 -5 years to begin to realize the expectations under which it was developed.

How are you going to assure that the CTSAAs maintain or enhance services currently provided by the GCRCs, including specialty nursing care, patient facilities, laboratory testing, and specialized monitoring and diagnostic capabilities?

Recognizing that General Clinical Research Centers support critical clinical research, the Clinical and Translational Science Award program allows applicants to request up to \$6M increase in annual costs above what is currently supported through General Clinical Research Centers. The additional funds may be used to transform the local, regional, and national environment for clinical and translational science, thereby increasing the efficiency and speed of clinical and translational research.

NIH anticipates that applicants for the Clinical and Translational Science Award program will retain services where useful to their clinical researchers, including inpatient and outpatient facilities, laboratory testing, specialized monitoring, and other services currently provided through the General Clinical Research Centers.

Have you considered maintaining a GCRC or mini-GCRC program for institutions that have had strong GCRCs historically, but do not receive CTSA awards?

The national CTSA consortium will not only foster novel collaborations among CTSA institutions but will reach out to other institutions through new partnerships, research opportunities, and community involvement. Through these and other efforts, the CTSA consortium will build a framework or matrix to energize the discipline of clinical and translational science throughout the nation.

Researchers may also apply for other funding opportunities at NIH, including Research Project and Research Program Projects and Centers grants. Research foundations, partnerships with industrial sponsors, and institutional funds also may provide additional sources of research support for investigators.