



The CTSA National Evaluation Final Report

Authors

Joy Frechtling
Kimberley Raue
Joan Michie
Atsushi Miyaoka
Maura Spiegelman

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Prepared for:
National Institutes of Health
One Democracy Plaza, 9th Floor
6701 Democracy Boulevard,
MSC 4874
Bethesda, MD 20892-4874

Prepared by:
Westat
1600 Research Boulevard
Rockville, Maryland 20850-3129
(301) 251-1500

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Executive Summary

The Clinical and Translational Research Program

Since 2006, the Clinical and Translational Science Awards (CTSA) program has been funded by the National Center for Research Resources (NCRR), a part of the National Institutes of Health (NIH). Designed to accelerate the pace of discovery and promote the translation of research findings to improve health care, the CTSA program began in 2006 with 12 medical research centers and has expanded yearly. In fiscal year (FY) 2011, it reached its full complement of 60 medical research centers. At the end of 2011, NCRR was dissolved; the National Center for Advancing Translational Sciences (NCATS) was established, and the CTSA program was moved to NCATS.

The National Evaluation

The initial evaluation of the CTSA program (February 2009 to February 2012) examines the program as implemented under NCRR, providing an early assessment of whether, and in what ways, the program has succeeded in enhancing institutional capacity for conducting clinical and translational research and advancing scientific knowledge. This three-year study, conducted by Westat as an external evaluator, focuses primarily on the progress of the first 46 CTSA programs that were funded. It was designed both to provide baseline data for tracking CTSA program accomplishments over time and to lay the groundwork for continued evaluation as the program matures and evolves.

Evaluation Questions

This initial evaluation has been guided by the following questions:

1. Are CTSA programs *increasing the quality* of clinical and translational research through scientific breakthroughs (knowledge, tools, and methodologies) and creating more streamlined and cost-efficient processes?
2. Are CTSA programs enhancing *collaborations* among institutions, disciplines, and researchers along the clinical and translational research continuum?

3. Are CTSAAs *enhancing the capacity* to conduct clinical and translational research, including supporting a *diverse workforce* that is distributed along the clinical and translational research continuum?
4. Is the CTSA Consortium providing *added value* to the program? How does the CTSA Consortium influence institutional activities and how do the institutional activities influence the Consortium?

The purpose of the present report is to address these four questions and synthesize what has been learned about them through the various substudies and data collection activities. As such, it is not meant to be a comprehensive tabulation of all findings from the evaluation; readers are invited to consult the substudy reports for additional information, as indicated below.

Design and Methodology

The evaluation comprises data collection approaches that combine broad-based surveys to gather quantitative data, in-depth case studies to enhance understanding and recognize the role of context, secondary analyses of extant data, and targeted comparisons where benchmarks can be identified such as citation rates from bibliometric analyses. To the extent possible, the six substudies that make up the evaluation have been designed to complement one another, with each evaluation question being addressed through multiple means and sources of evidence. This matrixed, mixed-method approach was deliberately selected to respond to existing design constraints, the complexity of the CTSA program, and the range of issues that its evaluation must address.

The design for the national evaluation builds on, and is guided by, the recommendations of the evaluation field. It has been designed to be responsive to the evolution of the CTSA program, to look at the program from a range of perspectives, employing multiple quantitative and qualitative methodologies, to triangulate findings and increase validity.

Evaluation Challenges

In reviewing the findings from this initial program assessment, it is important to keep in mind that the assessment is part of a continuing effort focused on examining critical, proximal outcomes expected from the program. Given the CTSA program is in the early stages, it cannot be a final or comprehensive evaluation of program outcomes. Outcomes addressing long-term impacts on the health of communities and the nation are not assessed in this study.

It is also important to recognize that evaluating the CTSA program is a challenge, not only because of its ambitious goals but also because of its many moving parts and the flexibility afforded the participating institutions. The CTSA program, like companion efforts at the NIH, addresses the goal of improving the health of our nation and transforming the medical research process to speed translation. At the same time, the program aims to reach these goals by making substantial changes in the research infrastructure and how medical research is carried out. The 60 sites that are now part of the effort all share these program goals and are expected to undertake substantial change in their infrastructure and cultures; recognizing the variation in the medical research centers and the communities they serve, the sites have been given license to do so in a variety of ways.

Findings

Study findings suggest that the CTSA program is making important strides toward encouraging and enhancing a new kind of medical research infrastructure and re-engineering the scientific research process. New practices are being established that have the potential to streamline and transform what is accepted as business as usual. A broad foundation is being established for conducting clinical and translational research.

In reviewing these findings, it is important to recognize that many of the changes associated with the CTSA program were not *initiated* by the program, but rather were *encouraged* and *facilitated* by the infrastructure it provides. The features of the re-engineered research model discussed below and throughout this report reflect an evolution in thinking that goes beyond the limits of any one program or funding stream. The value added by the CTSA program is to catalyze and integrate complementary streams of advances in ways that may lead to innovations, create new disciplines, and move the medical research process forward at an increasingly faster pace.

Key accomplishments and challenges identified by the national evaluation are presented below.

Key Accomplishments and Challenges

The CTSA program is implementing a variety of changes to the clinical and translational research process to enhance research quality and increase efficiency.

Accomplishments

The CTSA program has succeeded in providing research resources that enhance research, support innovation, and make the process more efficient.

- CTSAAs are catalyzing new approaches to research by bringing together new teams of investigators with complementary skills and knowledge.
- New academic homes are being created.
- Since the beginning of the CTSA program, 26,274 clinical and translational researchers have used the research resources. These resources are highly rated by investigators who have used them. The research resources offered through the CTSAAs have been especially important to supporting the work of new investigators.
- Biostatistics consultation and bioinformatics are making critical contributions to increasing the quality and efficiency of research, as well as changing the ways in which research questions are being approached and addressed.
- By creating a single portal for research resources, CTSAAs make it easier to identify and access services and tools to support clinical and translational research investigations.

The CTSA program is supporting important changes in how to integrate the pieces of the clinical and translational research process, as well as how individual researchers understand and move their own work forward.

A lot of people know about [the CTSA], and when I'm talking with colleagues, I'll say did you know you could take this discovery and bring it to the next level by interacting with [the CTSA]? That's what happened with me; I had a discovery in the lab, a small molecule that kills brain tumors without killing neurons. I was excited about this novel therapeutic approach, and the next step was to bring that into a mouse model. I interacted with the [CTSA] pre-clinical team, which is how I got to know experts in drug development, pathology, and mouse models. With their mentoring, I applied for and received a pilot award, and I'm now testing my technology in mouse models, and it's working. (Investigator)

The institutional pilot projects are especially effective in creating new research synergies and supporting junior faculty.

I've had three mentees who received pilot project funding. For one mentee, this led directly to a K23, and another former mentee is enrolling subjects in a novel clinical trial, which will likely become an R01 application; that was a CTSA-funded pilot grant, and that field of research would go nowhere without something like that. The pilot grants have been fantastic for me and the people I mentor. (CTSA mentor)

CTSAAs report a wide range of research that has the potential to lead to scientific breakthroughs. The publication records of CTSA-supported investigators suggest that researchers are highly productive, frequently cited, and making important contributions to the field.

Challenges

Awareness of the program is not as broad-based as it needs to be.

- There remains a substantial population lacking in adequate information about the CTSA's and what they can offer at both the institutional and national levels.

At the same time, demand for resources is taxing CTSA's ability to meet investigators' needs. CTSA's are having to establish new rules for access and new charging structures that may limit benefits.

The extent to which the research of the CTSA's will result in scientific breakthroughs is not yet known. While it can be argued that it is too soon to see such impact, determining whether the observed infrastructure and strategy changes lead to better science is essential over the next several years.

The CTSA's are fostering collaborations and partnerships that provide new approaches to solving complex problems.

Accomplishments

The CTSA program is supporting a range of *meaningful* changes in the collaborations across institutions, disciplines, and areas of medical research.

- New connections are being made between the pediatric and adult research areas.
- CTSA partnerships are creating new perspectives on how to address problems; findings from different spheres of knowledge are being drawn together to create new theories and produce new tools.

CTSA education and training programs expose junior investigators to research opportunities, people, and tools representing a wide range of points along the clinical and translational research continuum.

- Researchers with different backgrounds have the opportunity to think together and to design and carry out research together.

Examination of publications data shows that CTSA institutions are collaborating in publications and that there are increases in cross-site publication over time.

- According to the bibliometric analyses conducted, there were 442 inter-CTSA collaborations between 2007 and 2011. On average, each CTSA institution collaborates with about 16 other CTSA's.

The CTSA's are expanding efforts to engage the community and work collaboratively to address local health issues.

- Emergent efforts promote new collaborations, as well as build on existing networks.

Challenges

- The new connections among researchers and institutions that have been established are in some cases fragile due to lack of institutional incentives. Without continued incentives to work differently, old habits may reassert themselves. The clinical and translational enterprise is gaining strength but appears to be far from self-sustainable at this point.
- Progress in community collaborations is uneven. The community-related efforts vary from quite close to almost nonexistent; past history of interactions plays a significant role in determining current status.

The CTSA's are expanding the clinical and translational workforce through effective education and training programs.

Accomplishments

The CTSA program has been successful in providing expanded education and training support that are effective in educating researchers about clinical and translational research and exposing postdoctoral faculty and predoctoral students to new career paths.

- Since the CTSA program began, over 817 scholars and 992 trainees have participated in CTSA-supported education and training programs.
- The CTSA education and training programs are motivating junior faculty to explore pursuing a clinical and translational research career.

Key to the success of the programs is the strong mentoring component and the creation of protected time to do research.

The protected time is critical. Especially as a clinician, there's really no way that I would have been able to do the research, write the papers, write the clinical protocols. (Scholar)

Both mentors and scholar/trainees report that the CTSA education and training programs have a range of important impacts on scholars' and trainees' professional growth.

Challenges

There are a number of opportunities for program improvement:

- Continue to enhance ethnic diversity,
- Strengthen exposure to team science, and
- Expand attention to technology transfer and to communicating with the public and policy makers.

The Consortium gets mixed reviews.

Accomplishments

Although the organizational structure was criticized for its emphasis on process, the consortium has created a national network of academic medical institutions that fosters cross-site and regional collaborations.

The Consortium brings together the knowledge and resources from all CTSA, along with that of program directors (project collaborators).

Challenges

There is general agreement that the potential worth of the Consortium remains unproven and that the time spent on Consortium activities is not resulting in sufficient benefits. Now that the program has expanded to 60 sites, the existing organizational structure does not seem to be working well.

Recommendations

We offer several recommendations for NCATS and the NIH based on the findings of the evaluation.

Encourage institutional pilot programs

The CTSA program should continue to encourage investment in institutional pilot projects both by allocating CTSA program funds and encouraging individual CTSA to leverage additional funds to expand this component.

Increase researchers' awareness of the CTSA program and its resources

Researchers' level of awareness of the CTSA program and the opportunities it offers for clinical and translational is uneven. Continued effort should be made at the local CTSA level, as well as the national program level, to build the CTSA "brand" and inform stakeholder communities about what the CTSA are doing and can offer.

Expand education and training programs

The education and training component is successful and should be continued, even expanded to reach more junior faculty and predoctoral students, if possible. There are, however, opportunities for improvement in areas such as training in team science, strategies for technology transfer, and communicating with the public and policymakers.

The CTSA leadership should continue to explore strategies for increasing ethnic diversity in the clinical and translational workforce.

Streamline the functioning of the CTSA Consortium

Streamline the Consortium, reorganizing its structure and putting in place stronger management and oversight.

Consider creating a mix of regional and national efforts that interconnect individual CTSA's and their strengths.

Increase incentives for collaboration and partnerships

There appears to be some misalignment between the encouragement of collaboration as a central tenet of the re-engineered clinical and translational research model and reward systems that focus on individual accomplishments. NIH leadership should address the issue of inconsistencies in messages regarding the value of collaborative work, create positive incentives for collaboration, and encourage the modification of traditional tenure and reward systems at medical research institutions.

Conduct longer term evaluation

- **Study outcomes of CTSA-supported research on the health of communities and the practices of community clinicians.** Work both prospectively and retrospectively to evaluate longer term outcomes on scientific discoveries and health-related outcomes. Continue tracking and assessing potential scientific breakthroughs.
- **Conduct targeted studies of program components.** Conduct a study of the institutional pilot projects. The purpose of this study is not only to understand their contribution to the CTSA program, but also to identify models of support that might be considered best practices for broader dissemination to the Institutions and Centers (ICs) or other special support programs.

Explore technology transfer and how technology transfer is being supported and strengthened at the CTSA's.

- **Examine the efficacy of the Consortium as it is restructured and the contributions of the new coordinating center.** Continue to track and assess whether a real added value can be achieved through Consortium activities.
- **Work with local evaluators to develop metrics and measures and carry out evaluation studies.** Focus on establishing standard metrics, shared data collections, and coordinated research studies that can be aggregated to create program-wide information.
- **Establish and actively engage an evaluation advisory group of stakeholders.** Establish an evaluation advisory group that includes representatives from the PIs, local evaluators, IC leadership, professional associations, community groups, and outside evaluation experts.

The CTSA National Evaluation Phase 1 Final Report

The CTSA Program

Since 2006, the Clinical and Translational Science Awards (CTSA) program has been funded by the National Center for Research Resources (NCRR), a part of the National Institutes of Health (NIH). Designed to accelerate the pace of discovery and promote the translation of research findings to improve health care, the CTSA program began in 2006 with 12 medical research centers and has expanded yearly. In fiscal year (FY) 2011, it reached its full complement of 60 medical research centers. By the end of 2011, NCRR was dissolved; the National Center for Advancing Translational Sciences (NCATS) was established, and the CTSA program was moved to NCATS.

The CTSA program enables institutions to create an integrated academic home for clinical and translational science that has the resources to train and advance multi- and interdisciplinary investigators and research teams. CTSAAs engage basic, translational, and clinical investigators, community clinicians, clinical practices, networks, professional societies, and industry to develop new professional interactions, programs, and research projects. The CTSA program is designed to fundamentally change the organization and operating paradigm of research in major academic medical centers by providing infrastructure resources to support clinical and translational science activities and training for the next generation of scientists. Establishing new partnerships and new collaborations is considered essential to reaching the Initiative's goals. While many of the new linkages will involve direct collaborations among people or groups, new informatics tools are also expected to play an important role in deconstructing communication barriers that are endemic in the traditional academic research model.

Although most current CTSAAs previously had one or more General Clinical Research Centers (GCRCs), participating institutions vary along many dimensions. These include geographic location, size, public or private status, range and types of collaborating partners, pre-existing education and training opportunities, and previous history of community engagement. Many are also involved in local networks of medical research centers that include both other CTSAAs and non-CTSA research centers.

A key feature of the CTSA program is a Consortium that brings together the knowledge and resources from all CTSAAs, along with that of program directors (project collaborators). When established in 2006,

the Consortium formed committees that aligned with the key function areas outlined in the initial RFA.¹ In October 2008, Consortium members realigned the Consortium committee structure to support activities related to five newly articulated strategic goals: the enhancement of 1) national clinical and translational research capability, 2) training and career development of clinical and translational scientists, 3) Consortium-wide collaborations, 4) the health of communities and the nation, and 5) T1 translational research. The Consortium formulated new Strategic Goal Committees (SGCs) to draw on the expertise of the Key Function Committee (KFC) members and focused on identifying and accomplishing specific deliverables to support Consortium efforts. A Steering Committee, Child Health Oversight Committee, and Executive Committee were also included.

The role of the Consortium is to leverage cross-site strengths to create new clinical research management approaches, as well tools and resources such as shared databases, best practice documents, and curricula to benefit the overall program and, ultimately, the broader research field.

National Evaluation Overview

From its beginnings, evaluation has been an integral feature of the CTSA program. Evaluation occurs at multiple levels in multiple formats that include local institutional data collection and information tracking, monitoring by NCRR and other NIH program officers (project collaborators), and program-level evaluation by external evaluation experts. Indeed, program-level evaluation of the CTSA Initiative is expected by Congress according to the NIH Reform Act of 2006 and the Fiscal Year 2007 Appropriation Report – Senate – Report 109-287 and the Fiscal Year 2008 Appropriation Report – House – Report 110-231 (42 USC 242 b and 42 USC 282 b).

The initial evaluation of the CTSA program (February 2009 to February 2012) provides an early assessment of whether, and in what ways, the program is enhancing institutional capacity for conducting clinical and translational research and advancing scientific knowledge. This three-year study, conducted by Westat as an external evaluator, focuses on the progress of the first 46 CTSA's that were funded. Its purpose is to examine program accomplishments over time and lay the groundwork for continued program evaluation as the program matures and evolves.

¹ Administration; Biostatistics/Epidemiology/Research Design; Clinical Research Ethics; Clinical Research Innovation; Communications; Community Engagement; Education and Career Development; Evaluation; Informatics; Public-Private Partnerships; and Translational Research.

In reviewing the findings from this initial program assessment, it is important to keep in mind that the assessment is part of a continuing effort focused on examining critical, proximal outcomes expected from the program. Given that the CTSA is in its early stages, it cannot be a final or comprehensive evaluation of program outcomes. Outcomes of central importance to the program and NIH, particularly ones addressing impacts on the health of communities and the nation, are not assessed in this study, although some groundwork has been laid through the development of a database of a sample of potential scientific breakthroughs. (See the section Evaluation Approach and Methodology for a description of the substudies that compose the evaluation.) It is our expectation that the next phase of the evaluation will begin to take a hard look at this area of health outcomes.

This initial evaluation has been guided by the following questions:²

1. Are CTSA *increasing the quality* of clinical and translational research through scientific breakthroughs (knowledge, tools, and methodologies) and creating more streamlined and cost-efficient processes?
2. Are CTSA *enhancing collaborations* among institutions, disciplines, and researchers along the clinical and translational research continuum?
3. Are CTSA *enhancing the capacity* to conduct clinical and translational research, including supporting a *diverse workforce* that is distributed along the clinical and translational research continuum?
4. Is the CTSA Consortium providing *added value* to the program? How does the CTSA Consortium influence institutional activities and how do the institutional activities influence the Consortium?

The purpose of the present report is to address these four questions and synthesize what has been learned about them through the various substudies and data collection activities. As such, it is not meant to be a comprehensive tabulation of all findings; readers are invited to consult the substudy reports for additional information.

Stakeholder Engagement

In this evaluation, like many evaluations of groundbreaking efforts to improve the nation's medical and health research systems, there are many stakeholders in the enterprise. At the NIH level, aside from the CTSA program leadership, officials at NIH's Institutions and Centers (ICs) and the NIH Director's Office

² These guiding questions frame the evaluation and its boundaries. They were not presented in this form to any individuals involved in the substudies of the evaluation.

are interested in the progress of this program. Beyond NIH, Congress and other federal agencies involved with medical research and improving our nation's health clearly have a stake. The work is also important to the scientific research community, community organizations, professional associations, and health advocates, as well as evaluators of complex programs hoping to create systemic changes. While these varied groups have both shared and unique reasons for their interest, all are important and need to be genuinely involved. Recognizing this importance, deliberate efforts have been made both to solicit their viewpoints and provide information to them.

- **NIH has engaged stakeholders in a variety of ways.** In addition to formal reports on the program—some generated by the national evaluation; some by information gathered through other channels such as site visits or other monitoring activities—NCRR has brought representatives of these stakeholder groups together to discuss the CTSA evaluation, as well as the broader issue of evaluation of complex transformative efforts. The stakeholder meeting, held in July 2010, focused on determining what evaluation should address in the long term looking both at the CTSA program and other systemic, transformational efforts (Sufian and Mulligan, 2010).
- **The national evaluation has also reached out to stakeholders to help shape the evaluation's focus.** An initial step in designing the current phase of the evaluation was to hold interviews with a variety of individuals, both inside and outside of NIH, to obtain information on perceived purposes of the CTSA program and the kinds of information needed to evaluate its progress in both the short and longer terms. The outcome of these interviews was the development of the evaluation questions presented above. As the evaluation has progressed, Westat has continued to provide updates to the program and individual CTSA leaders through briefings at Consortium committee face-to-face meetings, conference calls, and formal reports on individual substudies.³
- **A major effort has been made to have ongoing communication with the local program evaluators.** This communication is important for increasing awareness of what the national evaluation is doing, better understanding the local evaluations, and creating bridges between the two. While at the outset of the national evaluation there was little interaction between the local and national effort, a close working relationship has been developed that has involved establishing a liaison group from the local evaluators to work with the national evaluation, joint development of a logic model for the CTSA program, creation of an evaluation white paper to guide future efforts, and establishment of a productive and ongoing dialogue on how to coordinate and improve evaluation efforts at all levels.

Special attention has also been given to listening to the questions and concerns of NIH program officers (now called project collaborators) and CTSA principal investigators (PIs) to address their information needs, as well as to help them understand how evaluation can inform and support their work. These

³ The national evaluation has worked especially closely with the evaluation Key Function Committee. A liaison group was established to work with the external evaluators to address both issues related to the Phase 1 research and the longer term external evaluation effort.

efforts have been, and need to be, ongoing to best serve the broader interests of the community. We will return to the role of stakeholder engagement in the concluding section, Recommendations.

Evaluation Approach and Methodology

Evaluating the CTSA program is a challenge, not only because of its ambitious goals but also because of its many moving parts and the flexibility afforded the participating institutions. The CTSA program, like companion efforts at the NIH, addresses the goal of improving the health of our nation and transforming the medical research process to speed translation. At the same time, the program aims to reach these goals by making substantial changes in the research infrastructure and how medical research is carried out. The 60 sites that are now part of the effort all share these program goals and are expected to undertake substantial change in their infrastructure and cultures; recognizing the variation in the medical research centers and the communities they serve, the sites have been given license to do so in a variety of ways.

From the point of view of evaluating the program, there is, therefore, no simple way to look at typical evaluation issues such as “fidelity of implementation.” Further, since the participating medical research centers have been chosen through a highly competitive process of application and review, identifying a control group against which to assess changes that may occur is not feasible. The approach taken builds on that recommended by the U.S. Government Accountability Office (2009) and others like Patton (2011), Trochim, Mark, and Cooksy (2009), Trochim et al. (2008), and Yarbrough et al. (2011), all of whom recognize the difficulty of evaluating complex, transformative systems, especially ones that are evolving while the evaluation is underway. These evaluators recognize that there are a variety of rigorous methods for conducting high-quality evaluation and maintain that it is important to creatively seek ways of gathering evaluation data, even when the traditional “gold standard” assessment, i.e., randomized treatment control studies, is not feasible and may not be appropriate.

The design for the national evaluation builds on, and is guided by, the evaluation literature described above. It has been designed to be responsive to the evolution of the CTSA program, to look at the program from a range of perspectives, employing multiple quantitative and qualitative methodologies, to triangulate findings and increase validity. As is true for all evaluations, it is limited by the nature of the data that are available (in this case, the quality of reporting in each institution’s Non-Competing Continuation Progress Reports (PHS 2590), the potential bias in self-reported survey data, and the lack of baseline data collected at the start of the program). However, it provides a design and methodology well

suited to examining program start-up and early accomplishments, while laying the groundwork for more long-term evaluation and assessment of progress.

The evaluation comprises data collection approaches that combine broad-based surveys to gather quantitative data, field visits (in-depth case studies) to enhance understanding and recognize the role of context, secondary analyses of extant data, and targeted comparisons where benchmarks can be identified, as with publications analyses. In addition to these formal study components, understanding of the operation and progress of the CTSA program was informed by attending annual face-to-face meetings of the PIs, evaluators, and administrators, and listening in to conference calls involving the SGCs, KFCs, and related workgroups.

To the extent possible, the six substudies that make up the evaluation have been designed to complement one another, with each evaluation question being addressed through multiple means and sources of evidence. This matrixed, mixed-method approach was deliberately selected to respond to existing design constraints, the complexity of the CTSA program, and the range of issues that its evaluation must address.

The six studies are as follows:

- *Analyses of publications data* to provide indicators of CTSA-related scientific advancements (publications study);
- *Analyses of Annual Progress Report data submitted* in the Non-Competing Continuation Progress Reports (PHS 2590) to understand basic program characteristics and statistics (APR roster reports);
- *Field visits* to a selected sample of nine CTSA institutions to obtain an in-depth, context-rich examination of how the program is being implemented and what it is accomplishing (field visit study);
- *Surveys of investigators* to assess the use and perceived value of resources (utilization study);
- *Surveys of scholars, trainees, and mentors* to assess the efficacy of the education and training component (education and training study); and
- *Development of a database of a sample of potential breakthroughs* to provide a starting point for examining the CTSA's scientific contributions to the field (potential breakthroughs database).

Publications Study

As part of the annual reporting process, CTSA's submit to NIH a list of publications stemming from research supported with CTSA research resources. Using these data as a starting point, along with data from the MedLine and Web of Science databases, Westat and Discovery Logic conducted a series of bibliometric analyses. These analyses provide information on publications produced by the program overall, by cohort, by year, and, in some cases, by CTSA institution.

Information reported includes a variety of statistics such as numbers of publications, types of publications, citation rates, Medical Subject Headings (MESH) terms, and collaborations. Where available, benchmark data are provided for comparison. Two reports are available, one including 46 CTSA's, covering the 2006–2010⁴ time period, *Initial Report on CTSA-Supported Publications: 2007 to 2010*. (Slaughter and Frechtling, 2011); and an updated report including 55 CTSA's, covering the time period 2006 through 2011, *Final Report on CTSA-Supported Publications: 2006 to 2011*..(Steketee et al., 2012).

Annual Progress Report Data

The CTSA institutions submit an annual progress report summarizing their previous year's accomplishments, including several rosters that provide individually identifiable information on users of CTSA research resources, scholars and trainees, and mentors. Westat has developed brief reports of these data that provide counts of investigators reported to have used CTSA research resources, mentors, scholars, and trainees. Summaries have been developed for the program overall, by cohort and year. The reports cover the APR years 2007 through 2010 and include data for 55 CTSA's.⁵

Field Visit Study

The purpose of the case studies conducted for the field visit component was to obtain an in-depth examination of how the CTSA program is being implemented and the progress CTSA's are making. A sample of nine CTSA institutions was selected for the visits, taking into account the following characteristics, as of 2010: cohort; geographic location; relative emphasis on basic research, pediatrics,

⁴ Data from 2006 cover a partial year in all cases.

⁵ Not all CTSA's provided data for all data elements, and the number of CTSA's responding varies by year.

and community engagement; size of award; affiliation with a Research Centers in Minority Institutions (RCMI) awardee, another NCRP program; and proximity of other CTSA institutions. The field visit study examined use of research resources, the education and training program, the culture for clinical and translational research that was developing, new collaborations and partnerships initiated by the CTSA, and perspectives on the Consortium. Findings are reported in *Report on Field Visits to CTSA*s (Westat, 2011).

Each visit was preceded by a review of information provided in each institution's Non-Competing Continuation Progress Reports (PHS 2590). NCRP program directors (project collaborators) were also interviewed. The field visits were conducted by three members of the Westat staff and a scientific advisor representing an NIH IC outside of NCRP. Over 300 interviews were conducted with institutional personnel and community members, including the project director, deans, department chairs, CTSA core directors, research investigators, mentors, scholars and trainees, evaluators, administrators, institutional partners, and community members.

Utilization Study

A key component of the CTSA program is the provision of research resources to investigators whose work falls at all points along the translational continuum. The utilization study, conducted in spring/summer 2011, was developed to explore the use of these resources, their perceived value, and the contribution they make to enhancing clinical and translational research work.

The study examined these issues through the lens of both research investigators who are reported in the Non-Competing Continuation Progress Reports (PHS 2590) to have used CTSA resources—"users"—and research investigators with NIH grants at the lead CTSA institutions who have not been reported to use the resources—"non-users." The samples for the surveys were drawn from data reported by 46 CTSA between 2006 and 2010.

Two Office of Management and Budget (OMB)-approved, web-based surveys were developed for the utilization study to gather data from users and non-users of CTSA resources. The study focused on the 46 institutions in the first four cohorts of CTSA awards. A total of 302 users and 537 non-users responded to the survey from these institutions. Results are presented in *Findings from the CTSA National Evaluation Utilization Study*. (Rau et al., 2011).

Education and Training Study

The education and training component is another key element of the CTSA program. Intended to enhance the capacity of researchers to do clinical and translational research, this component is designed to provide opportunities to learn more about clinical and translational research, appropriate research paradigms, and research skills. While many CTSA programs offer a range of course and workshop experiences for clinical and translational researchers and their teams, two groups of potential researchers are especially targeted—students working on their advanced degrees in the medical and social sciences (trainees, TL1 awards) and junior faculty who have attained their advanced degrees but may want to expand their research skills (scholars, KL2 awards). Integral to these components is a mentoring program, typically involving both primary and secondary mentors, that provides multi-year support to the researchers to enhance their clinical and translational research skills.

Two OMB-approved, web-based surveys were developed for the education and training study to gather data from CTSA-supported scholars and trainees and their mentors on the programs' activities and impacts. The study focused on the 46 awardees participating in the first four cohorts of CTSA awards. The data cover reporting years 2006–2010. All scholars and trainees reported were included in the sample. The sample of mentors included those reported for the 2009 and 2010 years. A total of 665 mentors and 553 scholars and trainees responded to the survey. For results see *Findings from the CTSA National Evaluation Education and Training Study*. (Miyaoka et al., 2011).

Database of Potential Scientific Breakthroughs

To begin tracking CTSA-sponsored research that might lead to scientific breakthroughs, Westat asked PIs at the field visit sites to nominate work that they felt could potentially lead to scientific breakthroughs. Additional nominations were also sought through the NCRR Office of Communications. The request asked for information on the project, the PI or co-PIs, a narrative describing the research, type of advance anticipated, grant support received, any collaborations involved, date initiated, and publications to date. The database currently contains approximately 50 nominations.

No further follow-up was conducted on the nominations as part of the Phase 1 evaluation. However, discussions with a range of stakeholders suggest that important next steps are to provide expert review of the nominations and set up a mechanism for tracking them. Recommendations for next steps are discussed in more detail at the end of this report.

Outcomes to Date

This section summarizes findings with regard to the four evaluation questions examined in Phase 1 of the CTSA national evaluation.

Question 1. *Are CTSA's increasing the quality of clinical and translational research through scientific breakthroughs (knowledge, tools, and methodologies) and creating more streamlined and cost-efficient processes?*

Research Resources

There is substantial evidence that the CTSA program is providing valuable research resources to support the work of a large group of clinical and translational (CT) researchers.

Resource reach. The reach of the research resources is reported by interviewees at the field visit sites to be much broader than that of the previous General and Clinical Research Centers. A greater number of investigators are receiving benefits.

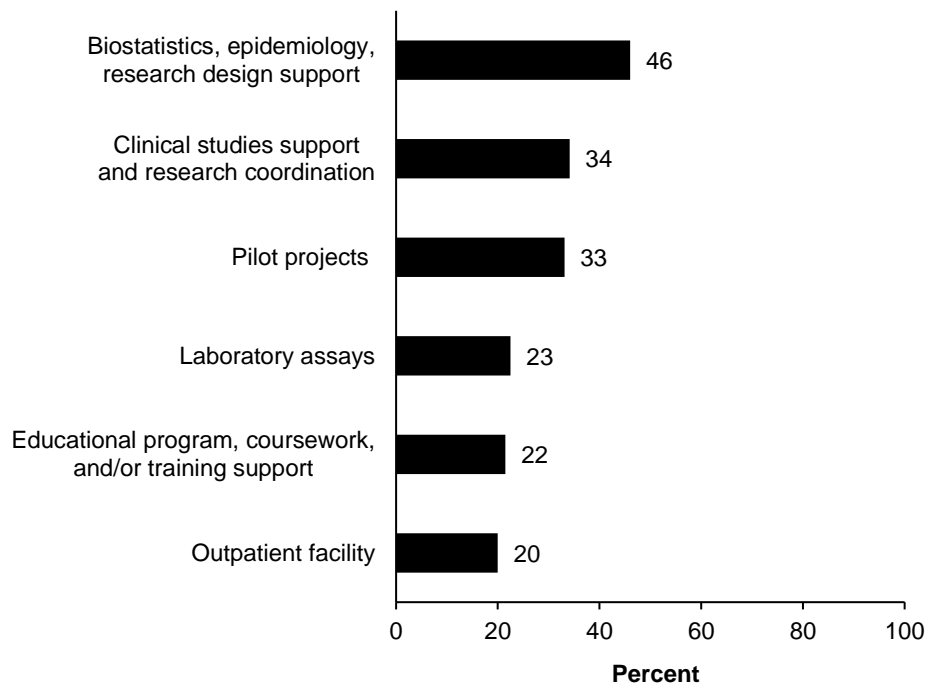
- Data from the annual progress reports indicate that since the beginning of the CTSA program, 26,274 clinical and translational researchers have used the research resources.

Value of resources. Although investigators reported benefiting from nearly 30 different types of research resources, five stand out as the most frequently used. Generally, these resources were also among the ones most recognized by those who had not used CTSA resources and were at the top of the list with regard to resources that might be used in the future (Figure 1). They are

- Biostatistics, epidemiology, and research design support;
- Clinical studies support and research coordination;
- Pilot projects;
- Laboratory assays; and
- Educational program, coursework, and/or training support.

Biostatistics consultation and bioinformatics were cited by interviewees at the field visit sites as making critical contributions to increasing the quality and efficiency of research, as well as changing the ways in which research questions are being approached and addressed.

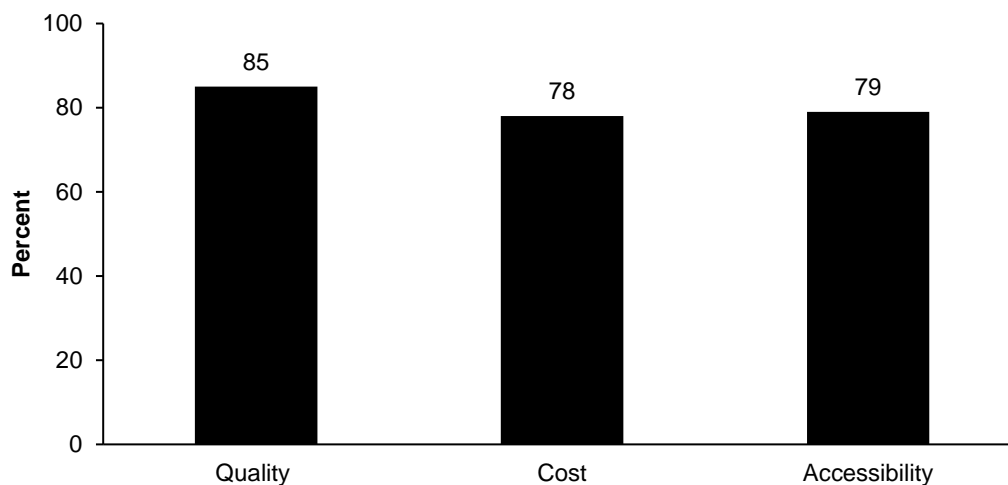
Figure 1. CTSA research resources users most frequently used (n = 302 users)



The research resources are viewed as making very positive contributions to the research being undertaken at the CTSA. Investigators who use the resources value them highly.

- Eighty percent of the 302 users responding to the user survey said they were satisfied with the resources; 88 percent said they would use them again.
- Around 80 percent rated the quality, accessibility, and cost of these resources very positively (Figure 2).

Figure 2. Users' overall ratings of CTSA research resources on quality, cost, and accessibility (n = 302 users)



NOTE: Based on respondents who answered good or excellent.

Pilot projects. Institutional pilot projects that provide small amounts of money to seed new research efforts were repeatedly cited as being of great value and appear to be a CTSA success story.

- Pilot projects were cited by field visit interviewees as a tremendous benefit in supporting the work of junior faculty, providing initial data that could be used for developing a formal proposal. A mentor interviewed as part of the field visit study offered the following assessment.

I've had three mentees who received pilot project funding. For one mentee, this led directly to a K23, and another former mentee is enrolling subjects in a novel clinical trial, which will likely become an R01 application; that was a CTSA-funded pilot grant, and that field of research would go nowhere without something like that. The pilot grants have been fantastic for me and the people I mentor.

- Pilot projects also benefited more senior researchers by incentivizing new linkages between researchers from different disciplines, departments, and institutions.
- Consistently, the interviewees in the field visit study provided examples of researchers receiving follow-up funding—such as R01 grants—based on work initiated with pilot grants.

The follow-on awards from [those] pilots is \$13 million I believe. So, they've more than doubled and leveraged the amount of the award. From the pilots we've given out so far, and we're talking three years worth of data, we've gotten five peer-reviewed scientific publications, 50 abstracts and oral presentations, \$13 million of follow-on funding from local awards and from the ...region... [an] extra, \$5 million of follow-on funding. Now,

from the amount of awards that we've given, that's a huge amount of follow-on funding. (CTSA PI)

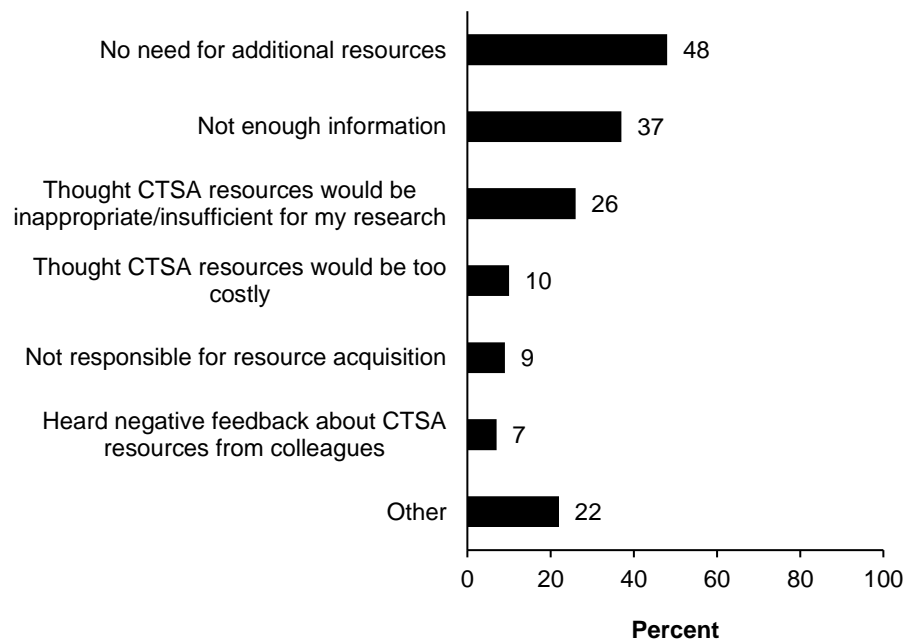
Awareness of Research Resources

Knowledge uneven. Awareness of the new research resources and what they can offer is still uneven.

The surveys documented uncertainty among some groups of investigators as to the source of the supports they used.

- According to the survey data, researchers who had not used CTSA research resources were frequently aware that they existed but did not use them because of insufficient information about them or a lack of need. Specifically, 48 percent reported that they did not have a need for additional resources and 37 percent reported a lack of information about CTSA resources (Figure 3).

Figure 3. Reasons non-users have not considered using CTSA research resources (n=100 non-users)



Integrating Research Along the Clinical and Translation Research Continuum

Connections across the research continuum. The CTSA program is supporting important changes in how to integrate the pieces of the clinical and translational research process, as well as how individual researchers understand and move their own work forward.

- There is an emerging recognition of the value and importance of translational research and deepening investigators' awareness of how they can move from a basic discovery to a practice for enhancing health. The following quote from a CTSA research investigator interviewed during the field visits captures the sense of the transformative influence of the CTSA program.

A lot of people know about [the CTSA], and when I'm talking with colleagues, I'll say did you know you could take this discovery and bring it to the next level by interacting with [the CTSA]? That's what happened with me; I had a discovery in the lab, a small molecule that kills brain tumors without killing neurons. I was excited about this novel therapeutic approach, and the next step was to bring that into a mouse model. I interacted with the [CTSA] pre-clinical team, which is how I got to know experts in drug development, pathology, and mouse models. With their mentoring, I applied for and received a pilot award, and I'm now testing my technology in mouse models, and it's working.

- Team science is changing the way people approach challenging problems and has a considerable impact on how research is being carried out in many places.

Creating academic homes. Many CTSA's are building new structures to bring together their clinical and translational researchers, as well as providing new academic homes. Boundaries between researchers at different points along the continuum are becoming more permeable.

- Many of the CTSA's visited are creating new physical spaces to bring clinical and translational researchers from different areas together to foster interactions.
- The CTSA's are recognized as having an impact on their home institutions that is integrative and widespread. Indeed, drawing a circle around what is the CTSA and what is the rest of the institution appeared to be artificial, as boundaries (where they had existed) have become permeable in a number of ways. Exposure to clinical and translational training affected all parts of the academic institutions.

Publications That Advance Knowledge

Publication productivity. Research findings resulting from CTSA-supported research are making important contributions to the field through publication in high-impact journals; CTSA publications are widely cited.

- Research supported through CTSA resources has resulted in over 17,000 publications across the 2006 to 2011 time period.

- The five journals in which CTSA research is published most frequently included two multidisciplinary journals and have journal impact factors ranging between 4.3 and 9.4. The mean impact factor is 9.064 (Table 1).

Table 1. Top 25 journals, by CTSA publication count

CTSA publication count rank	Journal title	CTSA publications	Impact factor
1	<i>PLoS ONE</i>	341	4.351
2	<i>Proceedings of the National Academy of Sciences</i>	308	9.432
3	<i>The Journal of Clinical Endocrinology and Metabolism</i>	246	6.202
4	<i>The Journal of Biological Chemistry</i>	194	5.328
5	<i>Diabetes Care</i>	183	6.718
6	<i>Blood</i>	172	10.555
7	<i>Neurology</i>	161	5.690
8	<i>Journal of Virology</i>	124	5.150
9	<i>Journal of Clinical Oncology</i>	121	13.598
9	<i>Circulation</i>	121	10.940
11	<i>Diabetes</i>	119	8.505
12	<i>Journal of General Internal Medicine</i>	115	2.964
13	<i>The New England Journal of Medicine</i>	111	51.296
14	<i>The Journal of Allergy and Clinical Immunology</i>	107	9.165
15	<i>Journal of the American College of Cardiology</i>	103	9.701
15	<i>Cancer Research</i>	103	7.543
17	<i>NeuroImage</i>	99	5.739
17	<i>American Heart Journal</i>	99	3.514
19	<i>The American Journal of Clinical Nutrition</i>	97	6.307
20	<i>The Journal of Infectious Diseases</i>	95	5.865
21	<i>Pediatrics</i>	93	5.012
22	<i>The Journal of Clinical Investigation</i>	92	15.387
22	<i>Clinical Cancer Research</i>	92	6.747

- Data also show that these publications are recognized by the field as important as evidenced by citation rates. On average, CTSA publications received about four citations one year after publication and about 11 citations two years after publication. CTSA publications are cited slightly more than similar benchmark publications.
- Scholars and trainees reported having substantial opportunities to engage in scholarly activities and develop publications (Table 2).

Table 2. Number of peer-reviewed journal articles as a result of research supported by CTSA-funded education and training program (n = 553 scholars and trainees)

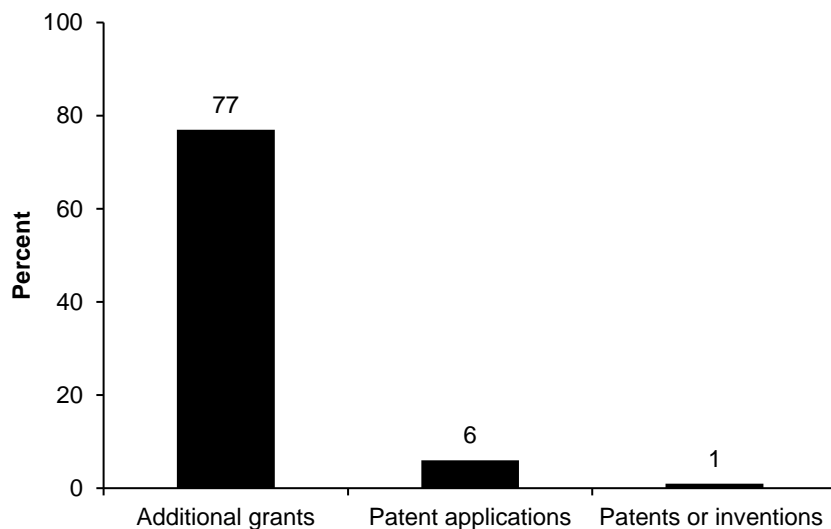
Authorship detail	Average number
Published	7.0
As primary author	3.7
With people from different disciplines	4.6
With people from different departments	4.7
With people from different universities/organization	2.6
With your mentor or mentors	4.4

Research topics. The body of knowledge produced by CTSA-supported researchers has its own profile. In particular, research dealing with HIV, obesity, the brain, cognition, polymorphism, diabetes, MRIs, genetic predisposition, cardiovascular disease, aging, and Alzheimer’s are all prevalent across CTSA.

Outcomes of Research

Results from research using CTSA research resources. A large percentage of users reported that the research for which they used CTSA resources helped them acquire additional funding. Smaller numbers reported applying for and receiving patents (Figure 4).

Figure 4. Grants, patents, and inventions resulting from use of CTSA research resources (n = 302 users)



Scientific breakthroughs. CTSA are beginning to identify CTSA-supported research that holds potential for producing scientific breakthroughs that can affect the health of the nation.

- When asked to identify research that has the potential to produce scientific breakthroughs, CTSA in the field visit study provided a robust list of research studies that they felt were promising. These research studies ranged from work on biomarkers for tobacco-smoke-induced lung injury, to development and evaluation of community-based buprenorphine inductions, to personalization of therapeutic efficacy and risk.
- It is important to continue to gather information on potential breakthrough research from the CTSA and to track the progress of these efforts over time to assess the scientific contributions being made by the program.

Question 2. Are CTSA's enhancing collaborations among institutions, disciplines, and researchers along the clinical and translational research continuum?

Partnerships and Collaboration Among Researchers

The CTSA program appears to be supporting a range of *meaningful* changes in the culture and norms of the institutions in which they are placed. New partnerships are being encouraged and are emerging.

Collaboration among investigators. Data from the field visits indicate that there is an emerging recognition of the value and importance of translational research and the benefits of working collaboratively across disciplines and institutions.

- CTSA partnerships are helping to close the divide between institutions and researchers serving pediatric and adult populations.
- Information from pediatric research is having a greater influence on research conducted with adults and vice versa.

The collaborations are creating new perspectives on how to address problems, with findings from different spheres of knowledge are being drawn together to create new theories and produce new tools.

Looking back 30 years, it used to be you were a basic lab scientist or you were a clinical investigator and those were two different worlds. And there was really no reason to really work across them. It was easier just to keep doing what you're doing. And I think the whole concept of the CTSA's has really made people interface. (Research partner representative)

The most important thing that it does is it provides a rallying cry and it heightens institutional awareness because it's brought up a lot that this translational thing is really important. It wasn't unusual to hear some of the basic scientists say, "Well, I'm studying this and I don't really care about disease. I'm interested in it because it's the way life is, and I want to know basic biology and I don't really give a darn if it has anything medically related." And you hear that a lot less now. So, you want transformation, that's the transformation. (PI)

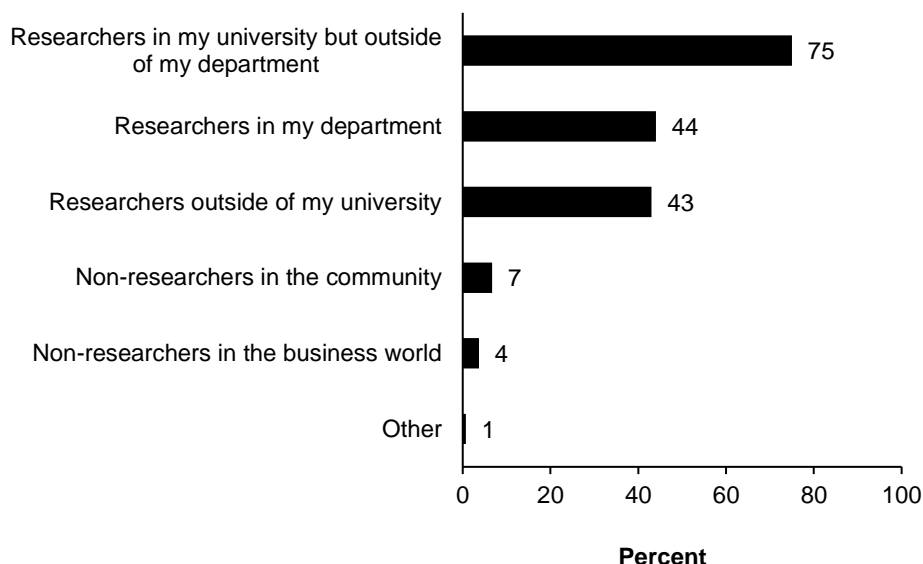
Collaboration among scholars and trainees. CTSA education and training programs expose junior investigators to research opportunities, people, and tools representing a wide range of points along the clinical and translational research continuum. One result is that researchers with different backgrounds have the opportunity to think together and to design and carry out research together.

- The CTSA education and training programs provide junior researchers with opportunities to turn their research work into peer-reviewed publications. Out of the seven peer-reviewed publications that resulted from research carried out as part of the CTSA education and training component, about five were published with people from different disciplines or from different departments and about three were published with people from different universities/organizations.

Role of research resources. Investigators who have used CTSA research resources also report that these resources have fostered increased collaboration.

- A large percentage of the 302 users responding to the survey indicated that the use of CTSA resources had a positive impact on collaboration, with 44 percent of respondents reporting that new collaborations were formed and an additional 25 percent reporting that existing collaborations were strengthened.
 - New collaborations generally formed around the submission of a new grant application (62 percent) and, to a lesser extent, research on an existing grant and co-authorship on a paper for publication (50 and 46 percent, respectively).
 - Half of new collaborations were described as having occurred multiple times, while an additional 42 percent were one-time collaborations that were expected to continue; only 5 percent of new collaborations were described as “one time only.”
 - Most new collaborations were related to clinical research interests (56 percent), followed by those related to basic biomedical research (31 percent).
 - While users most frequently collaborated with other researchers within their university or business, almost half (43 percent) collaborated with researchers from other organizations, for example, universities, companies in the private sector, and nonprofits (Figure 5).

Figure 5. New collaborations related to use of CTSA research resources (n = 134 users)



NOTE: Based on respondents who had formed new collaborations.

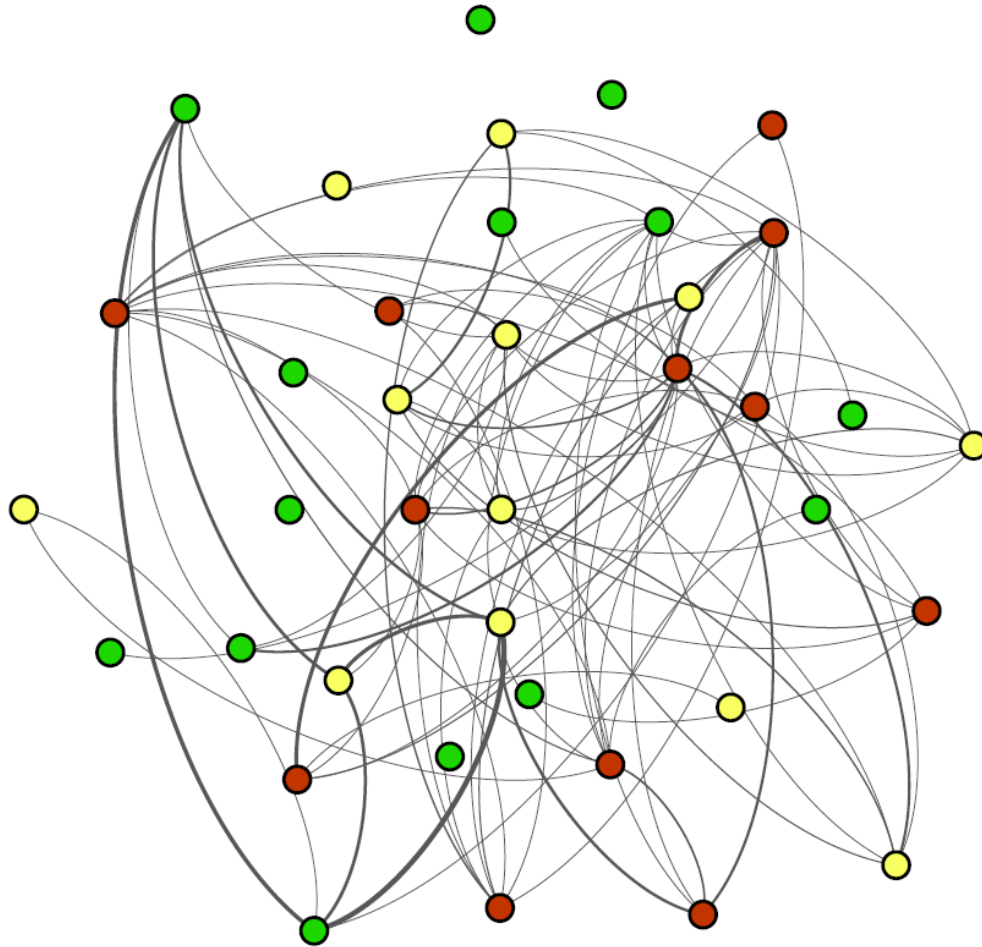
Collaboration in Publications

Cross-site work. Examination of publications data also shows that CTSA institutions are collaborating in publications and that there are increases in cross-site publication over time.

- Overall, there were 442 inter-CTSA collaborations between 2007 and 2011. The majority of these collaborations were 2010 publications. Between 2009 and 2010, both the average number of collaborations per CTSA and network density of collaborations substantially increased. Overall, on average, each CTSA institution collaborates with about 16 other CTSA.
- Figures 6 and 7 show changes in the numbers and patterns of collaborations between CTSA at the beginning of the program (2007–09) and the sum of collaborations to date (2007–11).
 - Comparing the figures shows that there are inter-CTSA collaborations between institutions of the same cohort and of different cohorts, as well as recurring collaborations represented by thicker lines at both time periods.
 - The increase in the volume of inter-CTSA is apparent. By 2011, most institutions have several collaborations, while only a handful of CTSA remain disconnected.⁶

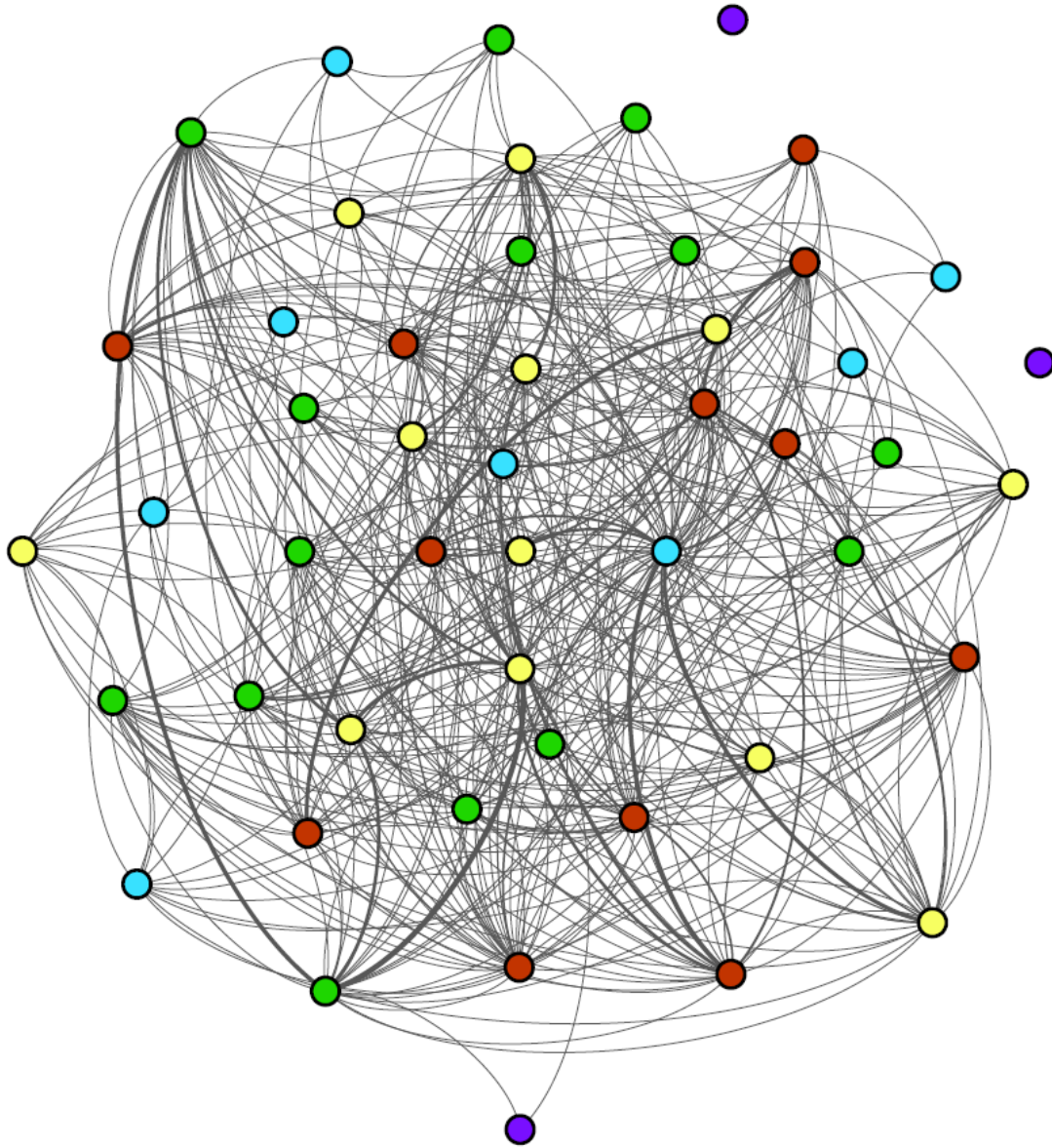
⁶ The unconnected nodes are CTSA institutions from Cohort 5, which have had little time to produce any publications.

Figure 6. Inter-CTSA collaborations based on shared publications between 2007 and 2009



NOTE: Nodes (circles) in this graph are color coded to signify cohort membership—red nodes are Cohort 1, yellow nodes are Cohort 2, green nodes are Cohort 3, blue nodes are Cohort 4, and purple nodes are Cohort 5. Lines between two nodes signify collaboration between two CTSA entities on a publication. The thickness of collaboration lines signify repeated collaborations, that is, when two CTSA entities publish more than one article together the line is thicker.

Figure 7. Inter-CTSA collaborations based on shared publications between 2007 and 2011



NOTE: Nodes (circles) in this graph are color coded to signify cohort membership—red nodes are Cohort 1, yellow nodes are Cohort 2, green nodes are Cohort 3, blue nodes are Cohort 4, and purple nodes are Cohort 5. Lines between two nodes signify collaboration between two CTSA on a publication. The thickness of collaboration lines signify repeated collaborations, that is, when two CTSA publish more than one article together the line is thicker.

Collaborations With the Community

Collaborations involving the community vary widely in strength and take place through many avenues.

Impact of past history. The field visits revealed that each site's history with its community has a tremendous effect on how this component is being approached.

- The community-related efforts vary from quite close to almost nonexistent. The CTSAAs visited started at different places with regard to community engagement and remain at different places today. Some are still at the foundational stage where trust-building is key; others have begun to develop new research components and work strategies, with CTSA researchers beginning to interact on research projects identified as important by the community. In some cases, institutional commitment to community engagement is being strengthened.

We've made significant investment in research in the community. That's been part of what we spent our CTSA money on, projects that bring together community-based organizations, health organizations in the community with researchers.... We used to call people up and say, can we do research on you and they'd say no. And now they say yes. We have the three CTSAAs in [the region] now working together on community-based research projects. It's another thing that would have never happened. (PI)

Focus on disease and disease prevention. The most frequent connections are evidenced in efforts to provide the community with a better understanding of diseases and disease prevention, as well as ones that attempt to educate the community about clinical trials and enroll patients in them.

The [community engagement unit] has allowed us to get out to the community for recruitment and to teach prevention and health. That wasn't there before. We didn't have a concierge team to help investigators with paperwork or the IRB. When it comes to doing the clinical studies, we have research aides that actually help investigators with the studies. (PI)

Building on existing networks. Some CTSAAs have taken the approach of strengthening already existing research collaborations that have existed in the community such as Practice-Based Research Networks (PBRNs). In three sites, PBRNs were mentioned as the jumping off point for strengthening community engagement. In three or four sites, evidence was provided of scholars whose research experience was embedded in a community health context or given examples of pilot funds targeted toward community-based research, but the engagement of scholars in the community is still far from widespread.

I'm interested in how to translate findings to the community, and [CTSA institutional partner] has ties with the community and people who are passionate about it. They have both the infrastructure and the will to translate basic science. What I'm doing—translating basic research and genomics into the community, making them participants in the research, and allowing them to work on the research—is unique. (Scholar)

Clash in value systems. There are challenges posed by the different interests of the researchers and the community, as well as the outcomes that they value. Researchers and community health workers think differently about health prevention and treatment (a focus on disease and treatments vs. a focus on life style and broader public health issues).

One thing we've had to grapple with is that the focus of our CTSA is primarily T1, and the community doesn't care about the discovery of a new drug or the mechanism of putting that into people; they're interested in violence, obesity, and diabetes, but [the community engagement core director] hasn't been able to tie this to the scientific focus of the CTSA. (Senior administrator)

Question 3. Are CTSA's enhancing the capacity to conduct clinical and translational research, including supporting a diverse workforce that is distributed along the clinical and translational research continuum?

Participation in the Programs

The CTSA's education and training programs are having significant impacts on the clinical and translational workforce.

Range of participants. The education and training component targets two groups of researchers—postdoctoral faculty who have attained their advanced degrees but may want to expand their research skills (scholars, KL2 awards)⁷ and predoctoral students working on their advanced degrees in the medical and population-based sciences (trainees, TL1 awards).

- Since the CTSA program began, over 817 scholars and 992 trainees have participated in CTSA-supported education and training programs.

⁷ The T and K awards represent only part of what is included in the overall education and training portfolio. Some CTSA's also offer training for others involved in the research process such as research managers. Most CTSA's also offer workshops of short duration that meet the needs of senior as well as junior researchers. It is, however, the T and K awardees who are the focus of these surveys.

- 52 percent of the 553 scholars and trainees responding to the survey classified their primary research as clinical; 21 percent indicated their work was in basic biomedical research; and 26 percent reported doing post-clinical research.⁸
- 51 percent indicated they have an MD; 11 percent indicated having an MPH; and an additional 31 percent held PhDs.
- Eight percent had an MD/PhD; 7 percent had an MD/MPH; and an additional 1 percent had a PhD/MPH.

Diversity. The education and training programs are, in many ways, succeeding in reaching a diverse group of researchers. There appears to be good gender balance in program participants with males comprising 43 percent of the participants and females 56 percent. However, increasing ethnic diversity is a priority needing continued attention as 70 percent of the participants classified themselves as white.

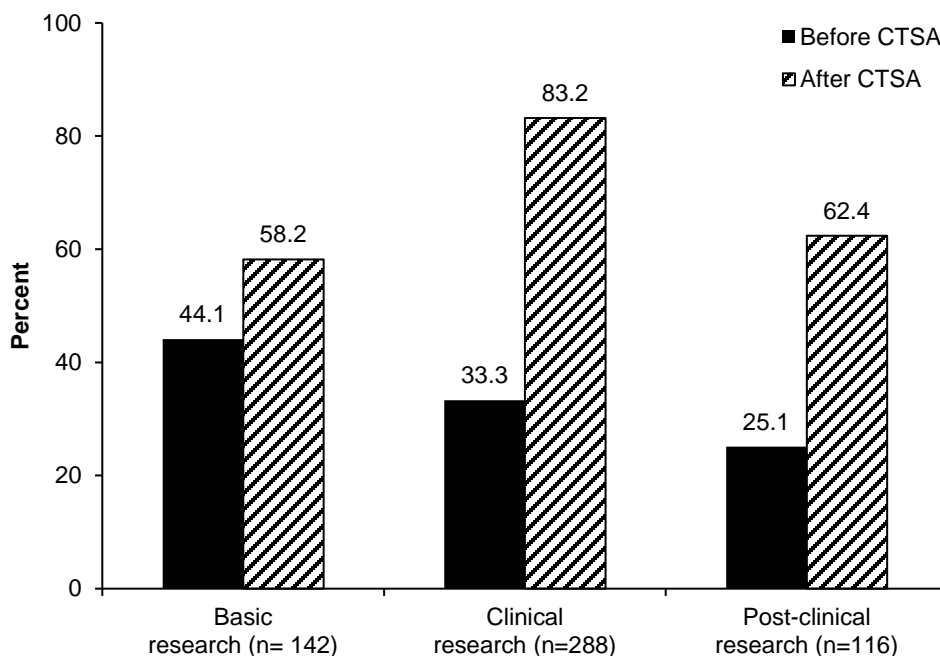
Scholars/Trainees' Assessments of the Program

Activities. Scholars and trainees were consistently positive about the value of the activities offered through various aspects of the CTSA-funded education and training programs.

- Over 90 percent indicated that engaging in research projects, working as a member of a research team, and building relationships with mentors were useful.
- 83 percent said that the laboratory work was useful.
- 33 percent of scholars and trainees assessed their levels of training and expertise in clinical research as moderate or high prior to their current CTSA program; 83 percent gave that rating at the time of the survey (Figure 8).

⁸ Post-clinical research typically involves the translation of new knowledge gained in formal clinical research into post-clinical or practice-based research. It may include phase 4 clinical trials, guideline development, meta-analyses and systematic reviews, community research, public or population health research, implementation or dissemination research, and health systems or policy research.

Figure 8. Self-assessment of training and expertise before and after the CTSA in three areas of translational research (n = 553 scholars and trainees)



Protected time. Key to the success of the programs is the creation of protected time to do research. Interviewees at the nine CTSA's visited as part of the field visit study consistently highlighted protected time as a key feature of the education and training programs.

The protected time for research, that's the predominant reason [I was interested]. I have a clinical background but I also teach at an academic institution. This [award] permits me to use protected time for research. (Scholar)

I knew I wanted a K award, and the benefit of the KL2 over the K12 or the K23 was that it provided 50% protected research time. As a surgeon, that protected time is critical to keep my surgical skills up to speed, and other surgeons will agree that 25% would have been enough time. I know several K23 surgeons who are struggling to build a surgical practice with that lower level of protected time, so that's one appeal of the KL2. (Scholar)

The protected time is critical. Especially as a clinician, there's really no way that I would have been able to do the research, write the papers, write the clinical protocols. (Scholar)

The mentor model. The mentor model built into the core of the program was identified as critically important to supporting the growth of scholars and trainees as CT researchers.

And so in my particular situation I don't think that there's a better mentor probably in the country or the world, with respect to ... cardiovascular disease and the translational research; it just doesn't get any better than that. I realize that what makes him so good is that he stays in touch with everything, meaning that literally he works at reading and always pushing himself to understand these new technologies and that he forces me to do the same. (Scholar)

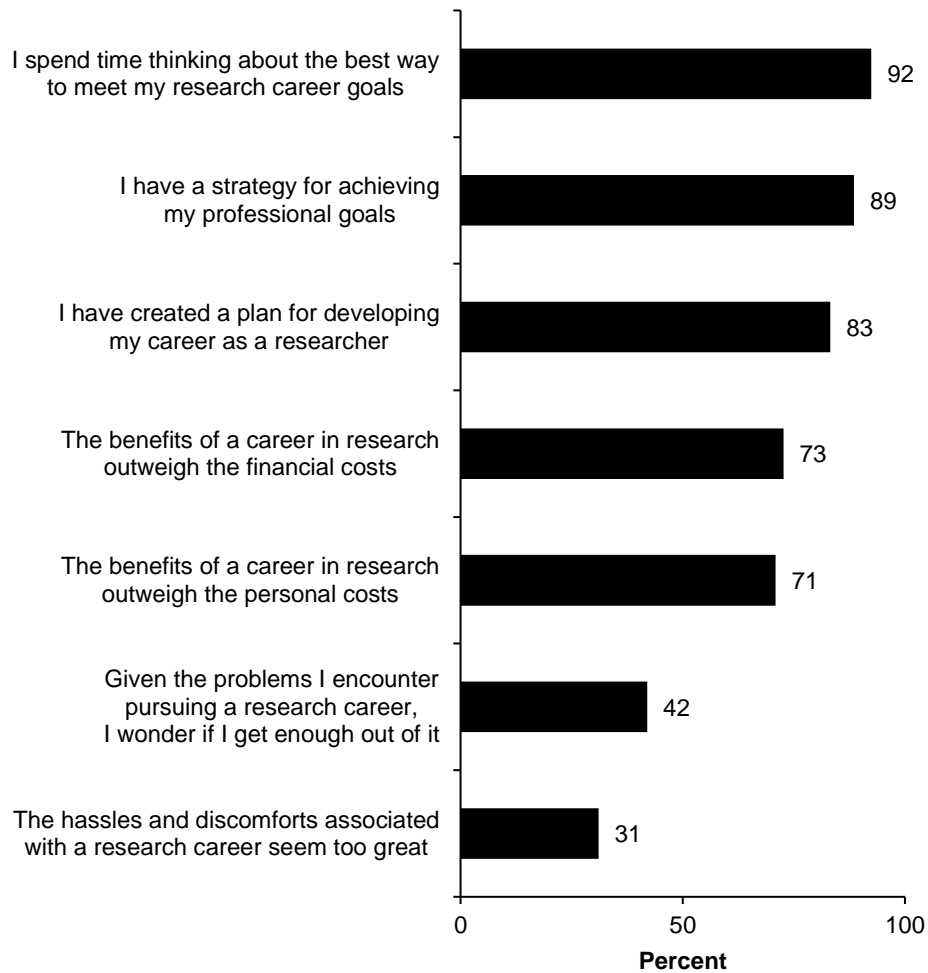
The mentoring program is one of the best aspects of the [CTSA education and training program]. (Scholar)

Impacts on Scholars and Trainees

Career paths. The CTSA education and training programs are viewed as making significant contributions to the size of the clinical and translational pipeline and the motivating of junior faculty to explore a clinical and translational research career.

- 96 percent of the scholars and trainees reported that their overall interest in a career involving clinical and translational research increased as a result of their participation in the CTSA education and training programs.
- 49 percent of those classifying themselves as basic biomedical researchers reported an interest in conducting clinical research, and 24 percent indicated an interest in conducting post-clinical research.
- The scholars and trainees report that the CTSA-funded education and training programs gave them a deeper understanding of the challenges of having a career in clinical and translational research. 89 percent reported they have developed strategies for achieving their professional goals as a result of their experiences (Figure 9).

Figure 9. Perception of various aspects of career in translational research (n = 553 scholars and trainees)



NOTE: Percents are based on scholars and trainees who agreed and strongly agreed.

New opportunities. Interviewees at the nine field visit sites were unequivocally positive about the opportunities the CTSA-supported education and training programs offer.

My background is biomedical engineering and I already thought of myself as thinking about translation and application, but I never really made that next step to what does it really mean. I've been thinking about other research projects, not only in bench research or even an animal study, but in clinical studies: surveying my patients, patient satisfaction, if certain surgical techniques are worth pursuing, is there something wrong here. These are things I would never have thought about: developing surveys, doing a focus group, or creating a survey. These are just completely new avenues of research that I would have never have thought about, but they're still relevant to what I want to do and what I'm interested in. So for me, it's opened up new doors. (Scholar)

Well, it's a great program. They're hoping to get a long-term academic career out of it. The original ones gave you five years of funding. So they're like a dream come true for a junior faculty if you can get one. And not only that but you're in this premier group and so you get to interface with those people. They have all these works in progress and they get mentoring. I mean getting the KL award here is like getting into the Ivy League. It's your ticket to success. If you look at the people who come out of that program, I think that they've had 90% success in getting academic positions. Incredibly high rate of getting ROIs...this is the premier program. (CTSA Partner representative)

Skills and knowledge. Mentors confirmed and reinforced the benefits reported by the scholars and trainees. Mentors reported that the education and training programs had a range of important impacts on scholars' and trainees' professional growth (Table 3).

- Mentors reported that 79 percent of their mentees were prepared to design and conduct clinical and translational research.
- Mentors reported that 84 percent of their mentees were prepared to communicate research findings.
- Mentors felt that 78 percent of mentees had effectively developed professional academic skills.

Table 3. Extent to which CTSA education/training program prepared mentees to engage in activities

Activity	Mentees (n=915)*
Design translational research.....	79.3%
Conduct translational research.....	77.2
Communicate research findings to others.....	83.8
Develop professional academic skills.....	78.0
Mentor other individuals who are affiliated with the CTSA.....	59.2

* Based on up to two mentees about whom mentors answered questions about their mentor/mentee relationship and were rated fully or moderately prepared.

Scholar and Trainee Accomplishments

Grants and publications. Scholars and trainees reported many accomplishments with regard to grant submissions and awards, as well as publications in peer-reviewed journals.

- 62 percent had the opportunity to work on a grant application; of these, 71 percent reported receiving funding.

- 16 percent reported submitting an application for an R01; 47 percent of their applications were successfully funded.⁹
- On average, scholars and trainees had seven peer-reviewed journal articles published based on work carried out through their research projects.

Impacts on Mentors

Benefits for mentors. Being a mentor in the CTSA program was also reported to have benefits for the mentors themselves. Their role offered them the opportunity to gain new skills and knowledge, as well as a better understanding of clinical and translational research. The experience was viewed favorably by the vast majority of the 665 mentors who responded to the survey.

- 57 percent reported that they increased their knowledge of issues affecting the translation of basic science into clinical treatments or interventions.
- 68 percent reported that the mentoring experience increased their understanding of scholarship within their primary areas of research.
- 67 percent reported that the experience increased their knowledge of issues related to the successful development of a research career.
- 97 percent rated their experiences as a CTSA mentor as positive.
- 91 percent would serve as CTSA mentors in the future.

Barriers to Clinical and Translational Research Careers

Traditional reward structures. Engagement in clinical research careers may be disincentivized by academic reward structures. Both senior and more junior faculty reported that tenure and promotion systems are more aligned with the career paths and activities typically undertaken by basic researchers. Attaining recognition and career advancement is more challenging when an investigator is engaged in team-based activities involving clinical or post-clinical studies that may take multiple years to produce results.

⁹ Trainees and scholars were asked to describe up to two grant/award applications on which they had the most responsibility since starting the CTSA education/training program. Findings from the first grant/award application they described are presented here.

Question 4. *Is the CTSA Consortium providing added value to the program? How does the CTSA Consortium influence institutional activities and how do the institutional activities influence the Consortium?*

Value of the Consortium

Mixed Assessments. Assessments of the value of the Consortium are mixed, with general agreement that its potential worth remains unproven according to data collected in the field visits to nine CTSA. While a number of valuable synergies have been created, and projects such as the IRB study and contracts study are having an impact on the management of the research process, implementing the Consortium has been challenging. Now that the full complement of 60 CTSA has been funded, creating and managing a national collaboration is facing new obstacles but continues to hold promise.

- The Consortium is seen as an important structure, one that is useful for sharing expertise and information, but, with its current structure of committees and workgroups, highly inefficient. Field visit interviewees faulted the Consortium for focusing too much on process and not enough on outcomes.
- In all sites visited for the field visit study, there were interviewees who could readily cite a benefit received from the Consortium regarding ideas, tools, or strategies. However, a substantial majority of interviewees associated the Consortium with long phone calls involving masses of people with relatively little payoff.

Conclusions

Taken together, these findings suggest that the CTSA program is making important strides toward encouraging and enhancing a new kind of medical research infrastructure and re-engineering the scientific research process. New practices being adopted by both individuals and institutions have the potential to streamline and transform what is accepted as business as usual. A broad foundation is being established for conducting clinical and translational research.

This movement is in its early stages of evolution but already poses opportunities and challenges both for institutions and individual researchers. The evaluation provides evidence for the following accomplishments and challenges.

Quality of Clinical and Translational Research

Accomplishments

- The CTSA program has succeeded in providing research resources that enhance research, support innovation, and make the process more efficient.
 - CTSAAs are catalyzing new approaches to research by bringing together new teams of investigators with complementary skills and knowledge.
 - New academic homes are being created.
 - The research resources offered through the CTSAAs have been especially important to supporting the work of new investigators.
 - By creating a single portal for research resources, CTSAAs make it easier to identify and access services and tools to support clinical and translational research investigations.
- The publication records of CTSA-supported researchers suggest that they are highly productive and are making important contributions to the field.
 - Citation counts affirm that these contributions are having a broad impact on the medical research being undertaken across the nation.
 - There are many exciting examples of work being undertaken that appear promising and have the potential for leading to new breakthroughs.

Challenges

- Meeting the increased demands for research support has emerged as a challenge. As the demand exceeds the supply, CTSAAs are establishing new rules for access and new charging structures that may limit benefits.
- There is uneven awareness of what the CTSAAs can offer. While many investigators who use the research resources are well acquainted with the program and its goals, there remains a substantial population lacking in adequate information.
- The extent to which the research of the CTSAAs will result in scientific breakthroughs is not yet known. While it can be argued that it is too soon to see such impacts, determining whether the observed infrastructure and strategy changes lead to better science is essential over the next several years.

Collaboration and Partnerships

Accomplishments

- The CTSA program is supporting a range of *meaningful* changes in the collaborations across institutions, disciplines, and areas of medical research.
 - Traditional structures that separate and isolate researchers are beginning to be broken down, and the value of strengthening interconnections recognized.
 - CTSA partnerships are helping to close the divide between institutions serving pediatric and adult populations.
 - Information from pediatric research is having a greater influence on research conducted with adults and vice versa.

Challenges

- The new ties that have been established are in some cases fragile due to lack of institutional incentives. Without continued incentives to work differently, old habits may reassert themselves. The clinical and translational enterprise is gaining strength but appears to be far from self-sustainable at this point.

Education and Training

Accomplishments

- The CTSA program has provided expanded education and training supports that are effective in educating researchers about clinical and translational research and exposing postdoctoral faculty and predoctoral students to new career paths.
 - The CTSA education and training programs are engaging participants in a range of research experiences along the clinical and translational continuum. The programs help researchers understand the connections between basic research, clinical research, and post-clinical research and applications.
 - The CTSA education and training programs are succeeding in attracting investigators to explore new areas of clinical and translational research, as well as providing them with a solid foundation of skills and knowledge.

Challenges

- While the education and training programs seem to be successful in diversifying the workforce in a number of ways, enhancing ethnic diversity remains a priority.
- Incentives for pursuing a clinical and translational research career are perceived to be inadequate, and traditional professional reward structures are not well aligned with proposed models of cross-disciplinary, cross-institutional collaboration.
- Exposure to team science, a key strategy in clinical and translational research, is uneven, and the CTSA's need to examine their adequacy of coverage in this area.
- Investigators are fully prepared for technology transfer and communicating with the public and with policymakers.

The Consortium Gets Mixed Reviews

Accomplishments

- Although the organizational structure was criticized for its emphasis on process, the consortium has created a national network of academic medical institutions that fosters cross-site and regional collaborations
- The Consortium brings together the knowledge and resources from all CTSA's, along with that of program directors (project collaborators).

Challenges

- There is general agreement that the potential worth of the Consortium remains unproven and that the time spent on Consortium activities is not resulting in sufficient benefits. Now that the program has expanded to 60 sites, the existing organizational structure does not seem to be working well.

It is important to recognize that many of the changes associated with the CTSA program were not *initiated* by the program, but rather were *encouraged* and *facilitated* by the infrastructure it provides. The features of the re-engineered research model discussed above and throughout this report reflect an evolution in thinking that goes beyond the limits of any one program or funding stream. The value added by the CTSA program is to catalyze and integrate complementary streams of advances in ways that may lead to innovations, create new disciplines, and move the medical research process forward at an increasingly faster pace.

Recommendations

For NCATS and the NIH on the CTSA Program

Encourage Institutional Pilot Programs

The CTSA program should continue to encourage investment in institutional pilot projects by allocating CTSA program funds to the pilot programs and encouraging individual CTSA to leverage additional funds. Some CTSA have already been successful in this area; at many others, the leveraging of funds is less visible.

- We also recommend program-wide tracking of how pilot funds are being allocated, the research being supported, and its results, including data on return on investment. Collecting such data could not only contribute to the understanding of the CTSA program's accomplishments, but might also provide information of value to other NIH programs that encourage interdisciplinary work or seek to engage new investigators.

Increase Researchers' Awareness of the CTSA Program and What It Offers

Researchers' level of awareness of the CTSA program and the opportunities it offers for clinical and translational is uneven. Medical researchers and community members need a clear understanding of what the CTSA is trying to accomplish and the roles the groups they represent can play in fostering scientific breakthroughs and medical advances.

- Continued efforts should be made to assess awareness and understanding of the CTSA program to identify where information is lacking and more targeted communication might be beneficial.
- Building the CTSA "brand" should be pursued at the local CTSA level, as well as the national program level. Increased awareness is important not only for helping to advance the research of individual investigators, but also for encouraging more far-reaching changes in the research culture, sustaining changes in attitudes toward clinical and translational research enterprise, and gaining the cooperation of the public in medical research efforts.

Expand Education and Training Programs

The education and training component is successful and should be continued, even expanded to reach more junior faculty and predoctoral students. There are, however, opportunities for improvement.

- From the point of view of program content, we recommend that a close look be taken at four areas found to be unevenly or not adequately addressed. They are the team science experience and training, strategies for technology transfer, communicating with the public, and communicating with policymakers.
- The CTSA leadership should continue to explore strategies for increasing ethnic diversity in the clinical and translational workforce. This objective should be pursued through strategies both for recruiting mentors from diverse backgrounds as role models and predoctoral students/postdoctoral faculty.

Streamline the Functioning of the CTSA Consortium

Findings regarding the Consortium indicate that this component of the CTSA program needs reshaping and re-conceptualization if it is to provide value added that justifies the time and resources needed to carry out Consortium activities. The new Consortium Coordinating Center can support this effort.

- Consider a mix of regional and national efforts that interconnect individual CTSA and their strengths. Currently, the focus is solely on activities that involve all, or volunteer samples of all, CTSA. Some cross-site collaborations may well need to be program-wide, but others may make more sense—and be more practicable—on a regional level.
- Reduce the levels of structure in the Consortium (strategic goal committees, key function committees, work groups) and establish more oversight with regard to tracking progress, sun-setting groups that are not being productive, and approving the initiation of new ones.

Increase Incentives for Collaboration and Partnerships

There is some misalignment between the encouragement of collaboration as a central tenet of the re-engineered clinical and translational research model and reward systems that focus on individual accomplishments. This is an issue for the field and NIH overall; it is not just a challenge for the CTSA program.

- NIH leadership should address the issue of inconsistencies in messages regarding the value of collaborative work. Setting up tangible rewards for collaboration within the program is a starting place.
- The CTSA leadership should engage IC directors and their staffs, as well as other key NIH leaders, in discussing this problem and developing ways that the NIH can be viewed as part of a new solution.
- The NIH voice and power could also be used to move individual institutions toward modifying their tenure and reward systems to acknowledge the value of team science,

interdisciplinary research, and cross-institutional collaboration (including interactions with both other medical research centers and businesses, as relevant).

For the Next Phase of the National Evaluation

Expand the Study of the Outcomes of CTSA-Supported Research

Work both prospectively and retrospectively in tracking the progress of research to evaluate the longer term outcomes of the program on scientific discoveries and health-related outcomes.

- Continue the examination of potential scientific breakthroughs and expand the database to include more CTSA. Several strategies for analysis are recommended: review of the candidate projects by expert panels, surveys of investigators to gather information on next steps in their research programs, and citation analysis to track the spread and utilization of findings in the field.
- Extend the examination of outcomes of CTSA-supported research by working with local CTSA evaluators to gather information on community health impacts of the work carried out by the CTSA. Use back-mapping to document the role of CTSA-supported research in bringing about these advances.

Conduct Targeted Studies of Program Components

Conduct a study of the institutional pilot projects. The purpose of these studies is not only to understand their contribution to the CTSA program, but also to identify models of support that might be considered best practices for broader dissemination to the ICs or other special support programs.

- Examine the development and outcomes of pilot projects of two different types: pilot projects that support the work of junior researchers and pilot projects that incentivize interdisciplinary collaboration. Pilots of different size and duration should be systematically sampled.¹⁰
- Study efforts designed to promote technology transfer and strategies for helping researchers move their work along the clinical and translational pipeline. Inventory and examine supports offered to take a basic research finding and move it forward to clinical trials addressing health needs.

¹⁰This work should build on the data collection currently being conducted by the Consortium to apply social network analysis techniques to understanding the development of new collaborative efforts.

Examine the Efficacy of the Consortium

Continue to assess whether a real added value can be achieved through Consortium activities. Assess the role of the new Coordinating Center in supporting restructuring.

Work With Local Evaluators to Develop Metrics and Measures

Continue and expand the collaboration with local evaluators. Focus on establishing standard metrics, shared data collection tools, and coordinated research studies data sources that can be aggregated to create program-wide information.

- Develop sets of core survey items to collect data that are administered CTSA-wide, along with supplemental modules targeted at specific interests of individual CTSA.
- Continue to contribute to work recently expanded by the Consortium to develop standard definitions for key program metrics (such as what “counts” as a CTSA publication) and encourage use of these metrics in data collection at both the local and national levels.
- Identify opportunities for local and national evaluators to work jointly on targeted special studies. The targeted studies of institutional pilot projects and technology transfer may be appropriate for this purpose.

Establish and Actively Engage an Evaluation Advisory Group of Stakeholders

One strategy for achieving stakeholder engagement that was not used in the current effort is the establishment an advisory group. We recommend adding this component in the next phase of the evaluation. Include representatives from the PIs, local evaluators, IC leadership, professional associations, community groups, and outside evaluation experts. Each of these groups has important contributions to the evaluation work through their specific areas of expertise. Engage this group as early as possible.

References

- Patton, M.Q. (2011). *Developmental Evaluation: Applying Complexity Concepts to Enhance Innovation and Use*. New York: The Guilford Press.
- Sufian, M., and Mulligan, L. (2010). Meeting Summary. Building a CTSA Evaluation Framework: Stakeholder Perspectives. Bethesda, MD: NCRR.
- Trochim, W., Marcus, S., Masse, L., Moser, R., and Weld, P. (2008). The Evaluation of Large Research Initiatives: A Participatory Integrative Approach. *American Journal of Evaluation*, 29: 8-28.
- Trochim, W., Mark, M.M., and Cooksy, L.J. (Eds.). (2009). *Evaluation Policy and Evaluation Practice. New Directions for Evaluation*. Hoboken, NJ: Jossey Bass.
- United States Government Accountability Office. (2009). *Program Evaluation: A Variety of Rigorous Methods Can Help Identify Effective Interventions*. Washington, DC: Author.
- Yarbrough, D.B., Shulha, L.M., Hopson, R.K., and Caruthers, F.A. (2011). *The Program Evaluation Standards: A Guide for Evaluators and Evaluation Users*, 3rd ed. Mountain View, CA: Sage.

Westat Reports

- Miyaoka, A., Spiegelman, M., Rau, K., and Frechtling, J. (2011). *Findings From the CTSA National Evaluation Education and Training Study*. Rockville, MD: Westat.
- Rau, K., Miyaoka, A., Spiegelman, M., and Frechtling, J. (2011). *Findings From the CTSA National Evaluation Utilization Study*. Rockville MD: Westat.
- Slaughter, A., and Frechtling, J. (2011) *Initial Report on CTSA-Supported Publications: 2007 to 2010*. Rockville, MD: Westat.
- Steketee, M., Frechtling, J., Cross, D., and Schnell, J. (2012). *Final Report on CTSA-Supported Publications: 2006 to 2011*. Rockville, MD: Westat.
- Westat. (2011). *Report on Field Visits to CTSA's*. Rockville, MD: Westat.