Request for Information:

Enhancing the Clinical and Translational Science Awards Program

Summary

June 14, 2012

National Center for Advancing Translational Sciences
National Institutes of Health
Department of Health and Human Services

Contents

Request for Information

The National Center for Advancing Translational Sciences (NCATS), part of the National Institutes of Health (NIH), sought comments from all key stakeholders on how to strengthen the Clinical and Translational Science Awards (CTSA) program to better meet its broad clinical and translational goals. In issuing this request for information, NCATS was seeking input from a broad spectrum of stakeholders including researchers; public and private partners who fund such research and services; and members of the public who are advocates, clinicians, patients and community leaders involved in the continuum of health care.

NCATS and CTSA

The mission of NCATS is to catalyze the generation of innovative methods and technologies to enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions. The CTSA program is an important component of this mission.

The CTSA program provides infrastructure to facilitate translational research, to promote the training and career development of translational researchers, and to develop innovative methods and technologies to enhance the field of translational research.

Prior to establishing NCATS, the NIH Director convened a trans-NIH working group to recommend a strategy for ensuring the CTSA program most effectively continued to improve translational research and human health. The working group made the following recommendations:

- **Continue to provide infrastructure support** for the full spectrum of translational research while encouraging CTSA institutions to develop their unique strengths.
- **Strengthen the cross-CTSA consortia activities** on both national and regional levels and plan for critical translational research needs on an as-needed basis in support of the NCATS mission.
- **Strengthen mechanisms for enabling interactions between the CTSA institutions and NIH institutes and centers (ICs),** including the development of suitable processes that allow the investment of IC funds in project-specific research, which will leverage the existing resources.
- **Evaluate each institutional award on its performance and allocate funds** based on performance measures that align with the goals of NCATS.
- **Allow current CTSA awardees to submit revisions to current awards prior to their anticipated renewal date** to enhance their strengths. These revised applications will be subjected to review.
- **Develop an explicit process for exchanging information** about the priorities, functions and expectations of NCATS as they further evolve.

Use of Results of the RFI

NCATS has reconvened the working group to advise on implementing these recommendations, and it also seeks public comment on how to better structure and position the CTSA program to develop novel designs, methods and research and enrich the translational pipeline.

The Request for Information

NCATS issued the RFI (NOT-TR-12-003) on March 6, 2012, with a response date of April 6, 2012. The Center proposed the following areas for comment by the key stakeholders:

1. Positioning the CTSAs to overcome one or more of the barriers in moving insights from research into and along the translational pipeline to inform clinical care
2. Fostering the role of the CTSAs in bringing better health to our communities through implementation and delivery research (e.g., innovative new approaches including mobile tools for outcome assessment, social media for community outreach, analytic approaches to assess health practices, and working with public and private sponsors for community outreach)
3. Identifying critical infrastructure investments that are essential to strengthening translational research (e.g., types of consultative services or clinical research facilities, possible sharing across sites)
4. Aligning resource allocation and needs and infrastructure use at individual sites and nimbly redirecting as needs change
5. Reducing the costs and time needed for implementing large, multi-site clinical studies — agree that an interoperable IT infrastructure and common financial management tools would be beneficial
6. Improving the protection of human subjects in ways that simultaneously will improve oversight and minimize burden and delays — strongly support central and reciprocal institutional review board (IRB) reviews
7. Encouraging shared investments with public and private funders, both nonprofit and for-profit (e.g., shared goal setting and metrics of success, redistribution or timing of risks and benefits)
8. Establishing priorities for shared, consortia activities across the CTSA sites as well as methods to encourage and support the high-priority activities
9. Measuring the value added of the CTSA program for science, the translational mission and the improvement of the nation's health

Responses to these topics other than these were invited, and respondents were asked to identify the critical issues and recommend approaches.

Comment Collection and Analysis

Responses to the RFI were received in an NIH mailbox and were sorted by the question(s) to which they responded. They also were considered for inclusion in this report of the RFI. As comments were received, they were collated into a single document of the full text of the responses. A list of the respondents' names and affiliations is at the end of this report (Appendix A).

Overview of Comments

A total of 139 responses were received. Responses came from individuals; representatives of CTSAs, academic institutions, patient advocacy groups, or community organizations; focus groups organized to give collated responses; and results of surveys/questionnaires to a representative group (e.g., CTSA). One response came from a consortium of 60 CTSAs. Of the 139 respondents, 118 were from 44

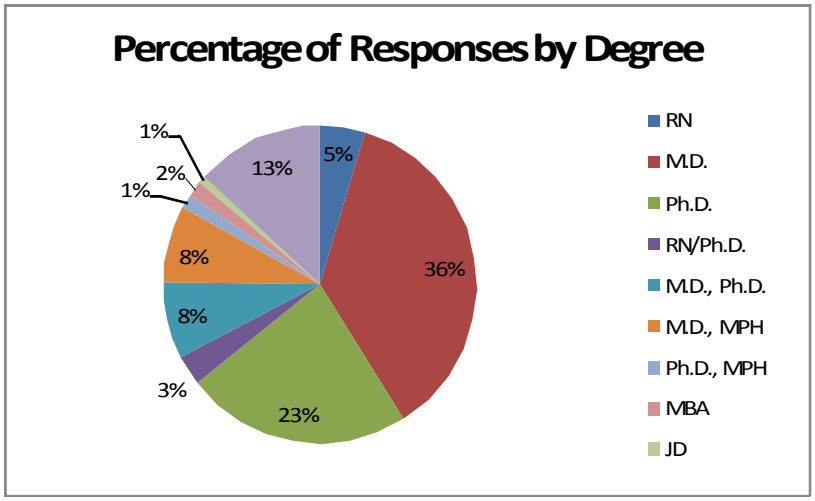
academic and hospital-affiliated institutions, the majority of which house a CTSA. The other 21 respondents' affiliations are shown in Exhibit 1.

Exhibit 1: Non-Academic Organizations Responding to RFI

AcademyHealth
Access Community Health Network
Advocacy Committee of the American Pediatric Society
American Academy of Pediatrics
Association of American Medical Colleges
Clinical Directors Network
Community-Campus Partnerships for Health
Critical Path Institute
CTSAconnect
CVPath Institute
Elsevier
Healthy Communities
ICF International
Immigrant Service Providers Group/Health
Lewis-Burke Associates/Primate Research Center
Remedy Informatics
Society for Clinical and Translational Science
Society of Behavioral Medicine
The Endocrine Society
The New York Stem Cell Foundation
Thomson Reuters

The respondents themselves represent a range of health care providers and scientists, as shown in Exhibit 2.

Exhibit 2: Percentage of Responses by Degree



Respondents clearly put a great deal of thought into their responses, which are rich with background, accomplishments, and hopes and plans for the future. The respondents' commitment to the process, to the CTSA program and to NCATS was evident. Some respondents answered all of the questions proposed, whereas others focused on only a few. Exhibit 3 shows the number of responses to each question. There was considerable overlap among the content of the responses to the questions, and although each response was labeled by a question number, its contents may have applied to other questions. The reviewers attempted to code the responses to questions, as shown in Exhibit 4; however, it is an inexact representation of the responses.

Exhibit 3: Number of Responses by Question

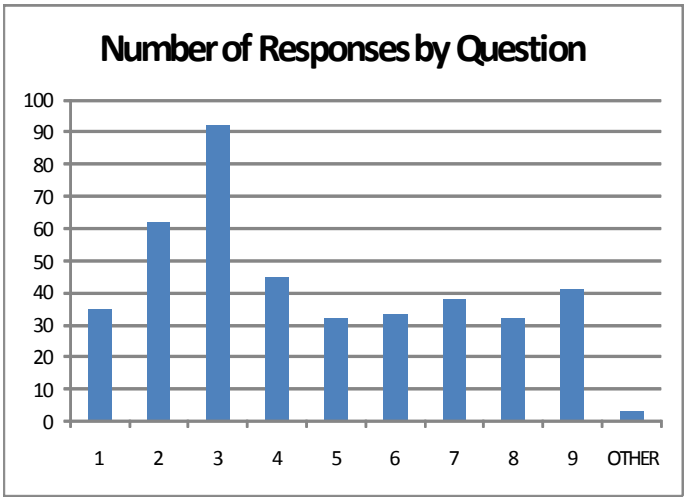
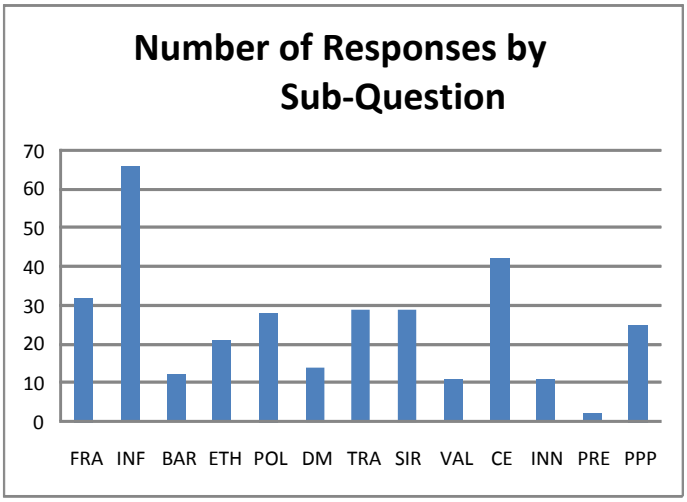


Exhibit 4: Number of Responses by Sub-Question



Key:	
Funding Resource Allocation	FRA
Infrastructure	INF
Barriers	BAR
Ethics	ETH
Policy	POL
Data Management	DM
Staffing/Training	TRA
Sharing Information/Resources	SIR
Measuring Value	VAL
Community Engagement	CE
Innovation	INN
Prevention	PRE
Public Private Partnership	PPP

Positioning the CTSAs to Overcome One or More of the Barriers in Moving Insights from Research Into and Along the Translational Pipeline to Inform Clinical Care

Several CTSA respondents indicated that their new "home" in NCATS positions them well to fulfill the mandate of translational research. They applauded the successes in building interdisciplinary teams of scientists, developing a translational research infrastructure and providing for training for many levels of scientists. They do, however, identify issues that create barriers to moving insights from research into and along the translational pipeline to inform clinical care.

A consortium of the 60 CTSAs summarized the issues: "Each of the now 60 CTSAs is unique, with different assets, capabilities and local challenges. All CTSAs struggle with limited resources, unfunded mandates and difficult priority decisions to address what has been the changing and evolving 'expectations' of CTSAs. The goals of research infrastructure

Definitions for Translational Research from T0 to T4

T0: Basic Scientific Discovery
Preclinical or "bench" research directed at mechanisms and presentations of human disease

T1: Translation to Humans
Testing basic science discoveries for clinical effect and/or applicability

T2: Translation to Patients
Testing new interventions in human subjects under controlled environments to form the basis for clinical applications and evidence-based guidelines

T3: Translation to Practice
Research on the application of new interventions or therapies in general practice; research that yields knowledge on best ways to implement new medical interventions in the clinic

T4: Translation to Population
Investigations of factors and/or interventions that influence the health of populations; ultimately results in improved health of the public

(Source: Southwestern Medical Center website)

building, greater efficiency of research processes, participation in national or regional CRO/consortia, education of the next generation of clinical and translational researchers, and the challenges of implementation across the full spectrum of T1-T4 translational research are enormous and can create ineffectiveness." Others echoed their concern that the mandate is now too broad, and priorities are not clear for moving forward. A representative summary of the widely used T0-T4 translational designations is provided above.

The dual priorities of supporting local activities and national, collaborative consortia activities make it challenging to fulfill both in an optimum way. The two roles for each CTSA — a common set of research services that permit efficient collaboration and a mix of unique resources derived from individual sites to meet larger goals (unique patient populations, unique scientific expertise) may be, at times, in conflict. There is a call for a better definition of who the CTSAs "are," and a set of priorities and funding to map the path forward.

One respondent, echoing a general concern about the need for greater communication among CTSAs, suggested regional collaboration would be enhanced and barriers to inter-CTSA collaboration reduced if a regional captain was nominated for a defined period. The captain would work collaboratively with the regional CTSAs to develop programs to be conducted at the regional level. The regional captains also would work at the national level with the Consortium Steering Committee to expedite translational pipeline initiatives including but not limited to: clinical trials, recruitment, drug and device development, biomarkers, and personalized medicine. In addition, annual meetings that would bring together all Key Function and Strategic Goal Committees would improve cross-communication and allow for the development of unique and creative ways of communication. Sessions would be structured to cut across boundaries and encourage communication and collaboration among the key groups to promote common consortia activities.

A common concern repeated throughout many of the responses was the need for more funding. The competing funding needs of early phase translational work and the need to support ethics, biostatistics, organizational research and community projects is a major challenge for CTSA leadership. Some respondents saw the focus on T1 research as a drain on the rest of the translational research pipeline as "duplicating efforts under way elsewhere," leaving little funding directed to clinical and community research, but others supported increased funding for early stage translational research.

A perceived barrier mentioned by many respondents was the difficulty in obtaining and/or reallocating funds. The respondents noted that a "fast-track" request and approval mechanism that would guarantee a quick turn-around and the ability to "carry forward" funds would allow projects to move forward more seamlessly. Respondents felt that the ability to re-budget and carry forward funds especially for seed funding projects is essential for research to continue at a fast speed.

In discussing the dichotomy between basic and clinical science, some respondents identified the lack of communication and established relationships among basic science researchers, clinicians and CEOs of companies who would like to invest in treatments. They suggested that shared definitions be developed to facilitate collaborative research between scientists and industry leadership.

There appears to be an undercurrent of concern that CTSA translational research stops at the clinic and does not reach out into the community. Respondents focused on inadequate funding; lack of infrastructure for communication among the academic, NIH, industry and community worlds; and little incentive to improve those relationships. Some respondents expressed concern that the needs of minority and underserved populations need more attention. Several respondents noted that the CTSAs have a unique opportunity to create a community that will welcome and implement new discoveries and cultivate an environment for research to reach its intended audience — the general public. Respondents indicated approaches to accelerate translation of research findings into public health practice through dissemination, implementation and diffusion research, a concentration on comparative effectiveness research and community engagement, and bidirectional commitment with the community to build trust and educate.

Another major theme involved regulatory compliance, particularly how regulatory requirements can slow down and inhibit research. The system for regulatory compliance is complex, institution-specific and time-consuming. There is a suggestion that additional regulatory expertise would be helpful in most CTSAs. According to many respondents, positioning the CTSAs to utilize one set of standards and streamline the research process would remove an important barrier to progress.

Training of academic colleagues, community-based physicians and community members themselves was seen by respondents as an approach to overcoming a barrier to getting new clinical techniques to the community. Training grants in translational research to junior scientists, workshops and programs for community-based physicians, and “town hall” meetings for potential study participants in the community would support the goals of translational research. An often forgotten asset is the teams of nurses, physicians, nutritionists, etc. who could be creatively engaged in the translational model of team care.

Respondents saw many opportunities to enhance informatics infrastructure at CTSA institutions to enable them to better accomplish CTSA goals. Strengthening the bioinformatics infrastructure and training CTSA members on its use would reduce redundancy, allow for the exchange of scientific and administrative information in real time, and eventually lead to greater cost effectiveness and efficiencies in reaching the target audiences. Incentives specific to informatics to help the CTSA consortium share and implement best practices would be helpful.

In summary, respondents indicated opportunities for CTSAs to improve communication within and across CTSAs, enhance community engagement, and support the need for cross consortia regulatory and informatics infrastructure.

Fostering the Role of the CTSA in Bringing Better Health to Our Communities Through Implementation and Delivery Research

The majority of responses to this question encouraged NCATS to continue the strong encouragement for community engagement and implementation and delivery research. Many respondents focused on the important role of CTSAs in communities and the impact the CTSA program has had. Some respondents

mentioned the potential impact of innovative new approaches such as mobile tools, social media and analytic approaches to assess health practices. Acknowledging the translational pathway begins with basic scientific discoveries and continues through clinical research; respondents noted that the translational pathway is only complete when it results in improved health of the public.

There were a number of concrete suggestions in response to this question. Some individuals proposed that community engagement address the need to complete the translational process through engagement of practitioners by means of practice-based research networks (PBRN). Others suggested CTSAs could play a role in the formulation, dissemination and implementation of practice guidelines and other policy-based approaches to advance care practices. Respondents proposed that the CTSA program is well positioned to translate science into practice and to address health disparities by engaging community partners together with multidisciplinary teams of scientists, health professionals and policymakers and to address underlying causes and eliminate disparities. Some respondents requested increased funding and an infrastructure for conducting more community-based prevention trials using the PBRN structure and other innovative community-based approaches. Respondents also noted that the additional time required to engage communities and develop viable research plans could be reduced if NCATS were to change its approach to re-budgeting and carry-over requests.

Respondents noted that CTSAs have been creating and supporting PBRNs in campaigns to promote volunteer participation in clinical research and in the enhancement of capacity to carry out community-engaged research through education of students, investigators and community members. They recommended that further support should be continued. Bidirectional communication between each CTSA and its local community is essential. Leveraging and funding programs and resources to better study and improve care for large underserved population groups are of the utmost importance. Including community representatives and potential community funders in local, regional and national meetings to plan and implement community activities would create commitment from both perspectives.

Nurturing this relationship was viewed as the most important strategy for efficiently moving scientific advances out into clinical care and for enhancing recruitment for clinical trials. The respondents stressed the importance of developing trust between the community and the academic medical center and establishing an ongoing conversation about the needs of the community and the offerings of academic research. It was expressed that health services can be delivered by community health promoters (e.g., promotores), such as nurse practitioners and dental technicians — at times more efficiently than by physicians. Some services also can be delivered via technological channels, such as wireless communication devices, to get the information to people where they are.

The need for improved communication was a consistent theme in fostering the relationship between the research community and the public. Targeted education and incentives (such as targeted RFAs) for dissemination and implementation research and strategies to improve general faculty awareness about methods and methodological issues related to dissemination and implementation research (e.g., seminar series, Web-based training opportunities or self-studies, visiting faculty) will improve the translational research effort. Effective communication could best be accomplished by incorporating

communication scientists with backgrounds in qualitative and quantitative methods, social marketing, behavioral theory, health literacy and social mediation to direct the activities. Health care advocates and *health promoters* were seen as a way to enhance the relationship between health professionals and patients, and as a means of encouraging patients to embrace advances in clinical care. Others suggested allied health professionals (e.g., nurses, dental technicians) play a more central role in engaging the community to implement new clinical advances in care.

The *CTSA Women in Clinical and Translational Research Interest Group* suggested that there needs to be greater diversity in the clinical and translational workforce. They believe diversity should be a specific program function within the CTSA agenda and metrics should be developed to document impact and change over time.

NCATS is encouraged to adopt innovative approaches to involving community representatives in the review of proposals that involve community engaged and community-based participatory research. Their involvement would help to develop the understanding and involvement among communities in research that will increase recruitment and continued participation, and to create through a community-based research infrastructure that puts the necessary capacity and skills to support research and improve community health.

Some respondents saw a key role for the CTSA in reducing the regulatory barriers to moving research from the clinic to the community and enhancing participant recruitment. The national CTSA program could provide leadership in these areas by creating templates of user-friendly consent forms and encouraging simplified medical registration forms. Further, building a strong and ongoing partnership with the community so that these relationships will already be in place before a clinical trial is initiated would decrease mistrust and enhance recruitment. Some suggestions included having the CTSAs provide resources for training community health promoters to recruit for clinical trials, identify best practices for clinical trial recruiting, provide resources to community organizations to compensate them for time/effort put out to recruit for studies and provide a nurse coordinator to act as an interface between the academic researchers and the community. Respondents also saw a need to engage existing physician networks in translational research.

Innovative tools for enhancing community engagement also were proposed. Some respondents suggested that CTSAs could employ innovative electronically derived measures of social disadvantage (e.g., numbers of address and emergency contact changes, homelessness, residence in a high-risk census track). Such tools would help identify targets for community involvement as well as their most pressing public health needs. The establishment of information exchange portals for real-time bidirectional communication with social service organizations to facilitate interventions outside health care settings, longitudinal perspectives of care, and increased access to services would help to build and sustain a relationship with the community and prepare them for upcoming projects.

The CTSAs could also continue to provide Best Practices of Community Engagement; notably, there is no NIH institute or center (IC) focused on funding projects that identify and disseminate the best methods of community engagement in research from a disease-neutral perspective. This has been a major

accomplishment and national contribution of the CTSA Community Engagement Key Function Committee.

Other suggestions included:

- Develop an SBIR mechanism to promote the development of mobile tools ("apps")/social media for patient recruitment, patient outcome reporting and clinical trial promotion.
- Create a "lessons learned" from other consortia that have been successful, or have identified otherwise unrecognized needs for infrastructure (VA, Gates Foundation, etc.).
- Expand regional collaboration to non-funded institutions to promote clinical and translational science to allow for sharing of training, community populations, lessons learned.
- Establish a website of clinical trials that is searchable by disease, and disseminate this information regularly to community-based physicians.
- Utilize new media platforms, point of care randomization strategies, new data mining tools for Electronic Health Records.
- Work with Centers for Medicaid and Medicare (CMS) to incentivize capture of outcome data as part of routine clinical care, remove regulatory barriers for including patient reported outcomes in the electronic health record.
- Develop methodologies for conduct of efficacy and effectiveness studies in the same trial.

By engaging communities in research, CTSA institutions are simultaneously developing the foundation for learning health care organizations and better integrated local health care systems. It was proposed that measuring the value added of the CTSAs must include considerations of how expenditures serve two purposes: support for research and improved public health. Additionally, infrastructure within communities that support research projects lessens the cost of additional studies while improving implementation and data collection. It further offers an increased likelihood that preliminary and final research findings will be shared with the communities and participants directly involved.

There were recommendations that the evaluation of the CTSAs' impact on the community should be gauged primarily by *how effectively the individual CTSA has addressed the health concerns that have been identified as a high priority by the surrounding community*. The CTSAs could take a leadership role in coordinating the process by which such priorities are identified by utilizing existing datasets that reflect health in the relevant region, determining whether the CTSA is recognized in the community as being a leader in translational research and engaging the community in determining additional metrics of success.

Identifying Critical Infrastructure Investments that Are Essential to Strengthening Translational Research

In the most recent RFA (RFA-RM-10-020), key function areas including biomedical informatics; research education, training and career development; community engagement and research; pilot projects in translational and clinical studies; and regulatory knowledge and support are all required with optional inclusion of development of novel clinical and translational methodologies; research design,

epidemiology, biostatistics and clinical research ethics (BERD); and clinical research resources and facilities.

Recognizing the value of the key functions both at local and national levels and their role in the discovery and development of new drugs, as well as dissemination and implementation of new drug therapy in the community, will be essential to positively impacting public health, the major goal of the CTSA program. Several infrastructure requests were made — either to maintain and grow existing infrastructure or to support new ones:

> Clinical Services Cores (Clinical Research Units [CRUs], former General Clinical Research Center programs) will be an essential part of NCATS' ability to test the new treatments it creates. Some respondents recommended that every CTSA should have such facilities and the national program should network these resources for multi-site trials. This feature was supported by many respondents, but most wholeheartedly by 35 junior faculty from a CTSA-funded institution who expounded on the value of the nursing, nutrition, coordinator and community health worker support.
>
> Biomedical informatics and bioinformatics infrastructure are necessary for furthering both institutional and NCATS goals in areas to include genomics, proteomics and the like.
>
> Interoperable information technology (IT) infrastructure was seen as of paramount importance to the growth and sustainability of the CTSAs. IT infrastructure recommendations also included training in use of systems and data management skills. The goal is for the CTSA to productively develop and support databases with patient-level data. CTSAs could determine how to most effectively combine electronic health records (EHRs) with clinical trial data. More CTSAs could contribute to the creation of therapeutic disease area standards and ensure that data are remapped to standards that would serve to accelerate FDA review. Informatics components of the CTSA initiative could be expanded to link to public health services researchers working to advance the effectiveness of local approaches to population health monitoring and improvement. These linkages will be vital to support full community-engaged research and translational activities that result in new and effective models of care delivery and improved population health.
>
> Inherent in the discussion of IT was the need for an infrastructure to support the use of EHRs for clinical research. More discussion focused on the growing need for the EHR to broaden the datasets available for clinical research and increase the efficiency, while decreasing the cost, of research projects. As a result, substantial effort has focused on building data warehouses that permit the reuse of data to support research (e.g., comparative effectiveness research) and application of clinical research analytics. Data models are needed that are robust enough to accommodate high volumes of data that translational research produces, the continuous introduction of new data elements (or redefinition of pre-existent ones), or the unanticipated and complex nature of translational queries. Thus, an infrastructure is required to conceptualize, build, implement, train and disseminate this resource.

Data management capabilities will enable CTSAs to capture, store, securely share and analyze data from electronic medical records and research project records. The ability to integrate these data across multiple institutions would support clinical and translational research by providing access to research results and their impact in clinical settings. CTSAs must engage in continued development of tools and technologies that enhance the network's abilities to share securely, de-identified patient data to facilitate research in responses to drugs, therapies, changes in practice, etc.

Education programs such as the CTSA TL1, KL2, Ph.D., masters, certificate and other programs are needed to teach students, faculty and staff how to design, conduct, translate and disseminate translational and clinical research. CTSA educational programs should both teach basic scientists to translate laboratory findings into clinical applications and teach clinicians to conduct clinical research and collaborate with basic scientists. A Grad-into-Med model should be incorporated for Ph.D. students and postdoctoral fellows, to introduce them to the conduct of clinically relevant research. Very few CTSAs have core capability in the methods of implementation research and improvement science. These areas of inquiry are rapidly evolving and these innovative approaches require newer qualitative and quantitative methods. The CTSA training programs — including KL2 and TL1 programs — could be used to advance innovative training programs and coursework on the methods of these and other evolving types of research.

Community engagement programs as discussed in response to Question 2 ("Fostering the roles of the CTSA…")

Clinical pharmacology pharmacokinetics/pharmacodynamics and Good Manufacturing Practice resources are pivotal for first-in-human studies, a common "valley of death" between T0 (basic discovery) and T1 (translation to clinic, see chart on page 7) research, and for alleviating the paradox that NIH does not fund first-in-human studies until an Investigational New Drug (IND) is approved; however, one cannot obtain an IND application without pharmacology and toxicology studies. Because of the high cost of these resources, they should be shared among CTSA sites or supported by NCATS through other means.

Support for the regional CTSA consortia to develop, implement and maintain clinical and translational resources and facilities for multicenter and multi-community projects such as clinical trials and community engagement and comparative effectiveness research (CER).

Closer alignment with the other NIH ICs, particularly those that use CTSA resources heavily, as well as those that invest in disease neutral support and administer infrastructure-type programs. CTSAs understand that accelerating the pace of drug/device/biologic development is a mission of the NIH. By providing the test bed for new innovations, CTSAs are positioned to support NCATS in becoming a central source of research efficiency knowledge for any disease.

Multifaceted research subject recruitment/retention program that includes protocol cohort assessments, best-practice accrual strategies and systematic performance monitoring. A team of

experts should be brought together to identify local and national best practice models for subject recruitment/retention, develop and manage tools for local recruitment, and organize protocol feasibility assessments to assure investigators make appropriate decisions at the various local sites.

Centralized, integrated regulatory processes will enable investigators to move among the many required approvals, especially in translational research. Infrastructure investment by NIH would allow for an integrated approval process which might encourage individual investigators to take the broader view of their research, rather than constraining their investigations to a slice of the translational continuum.

Core laboratories should be made available throughout the consortium by developing business plans and an information resource (database) to make the unique capabilities available to investigators across the CTSA consortium at reduced rates. This advance will permit CTSA sites to engage in a broader range of research, permitting wide-based collaborations. Examples include tissue collection and banking, genomics, proteomics, and unique equipment or facilities such as Biosafety Level 3 containment. High-cost instrumentation and infrastructure must be shared at least regionally.

Research nodes that can uniquely utilize technologies across the consortium. Through the consortium and regional groupings the CTSA consortium can identify unique facilities at other institutions that will facilitate and enhance utilization. CTSAs with special expertise — for example, in devices, drug discovery, diagnostics, special populations or outcomes-based research — should be encouraged and rewarded for excellence in a specific area.

Sharing facilities across regional and national consortia of CTSAs and among their community and disadvantaged partners, an activity that is under way, will enhance the translational research at all institutions while diminishing the distance between “have” and “have-not” institutions.

Aligning Resource Allocation and Needs and Infrastructure Use at Individual Sites and Nimbly Redirecting as Needs Change

Responses to this question addressed structural, functional and training aspects of aligning resource allocation. Overall, respondents were concerned about the imbalance in resources across CTSAs, budget flexibility and the breadth of activities required to be performed by each CTSA.

Respondents raised concerns about the position of the CTSAs within NCATS and wanted assurance that its placement within the Division of Clinical Innovation would not exclude some types of research currently supported by many CTSAs and would remove any barriers that would impede CTSAs from efficiently moving research through the translational pipeline. Respondents stressed the unique nature of each of the CTSAs and thus suggested the alignment of resource allocation to the needs of each center. Starting with the RFA, they would like to see funds directed in relation to the strengths and priorities of the institution rather than being directed by the RFA to respond in a specific fashion. It was

suggested that funding for the CTSA be locally broad in covering the translational spectrum, but consortium contributions should be focused on each CTSA's areas of expertise. For example, the path from T1 (testing for clinical effect) to T2 (translation to patients, see chart on page 7) requires support for training, pilot awards, experimental design, biomedical informatics, technologic and "omics" support, and a clinical research unit while T3 (translation to practice) requires funding to engage community and establish best practices.

Some respondents recommended allocating resources across the CTSA institutions according to a merit-based funding mechanism model, rather than the current model, based on each institution's historical National Center for Research Resources (NCRR) funding. They expressed concern that this historical formula allowed the large centers to "get richer" while keeping the small centers from getting additional funding or to increase their support for institutional activities except through other institutional support.

A related RFA budgetary concern was evaluating the proposed goals and progress of each CTSA without consideration for the size of the budget with which they have to work. It was pointed out that there is a four- to six-fold difference between the largest CTSA grant and the smallest, but the two are currently evaluated on the same criteria and expected to participate in national CTSA programs to the same extent. Smaller CTSAs will have fewer resources to both transform clinical and translational research at their own institutions and significantly contribute to the national CTSA goals. Another respondent proposed that resource allocation among the CTSAs consider other factors, such as geographic cost of living factors, which are reflected in salaries, rent and other infrastructure costs.

Although differences in CTSAs are clearly recognized, more effort should be directed at metric analysis for defining the strengths and outcomes at an institution. Some key functions, like education programs, can be judged readily, while others, such as improving the infrastructural support for all forms of research, across CTSA collaboration or community engagement, cannot. Respondents questioned how these attributes can be measured and asked NCATS to develop new metrics to determine funding.

One respondent suggested that CTSA evaluation be bidirectional and strategic, involving CTSA PIs and NIH officials as well as outside experts. This CTSA respondent offered that the process should be an evolutionary effort with clear-cut reasons for all decisions that are tied to the defined role of the CTSA in NCATS' mission.

Many respondents expressed the need for the "nimble" redirection of funds allowing interim re-budgeting, end-of-fiscal-year carryovers and the availability of frequent supplemental funding. Improvements to shorten delays and provide more accurate and consistent information will substantially alleviate burdens across the CTSA consortium. Some expressed concerned that NIH was directing them to pursue initiatives outside the original scope of the RFA. Redirecting resource allocation based upon public health need or scientific opportunity should always be considered, but not at the expense of the planned and fundamental elements necessary for complete support of clinical and translational research at the local level. Many respondents discussed this issue in the context of the CTSAs' potential role as a Clinical Research Organization (CRO). Several respondents did not support a CRO initiative with CTSA funds and believe ICs should leverage CTSA for large-scale studies rather than

expecting CTSAs to become CROs or that supplemental funding should be used to support the CRO initiative for those sites that wish to compete.

Several respondents reflected upon the various ways in which CTSAs attempt to cope with budget shortfalls without compromising the work of the CTSA. They support the use of competitive supplements as an effective way to stimulate collaborative and innovative activities among CTSAs in a way that is responsive to NCATS and IC needs. Although most CTSA programs now charge investigators for research support services, such as those provided by Clinical Research Units, this can have the unintended consequence of discouraging use by trainees and junior faculty who are often unable to cover these expenses from other funding sources. NCATS needs to provide flexibility to allow individual sites to provide these services in a way that makes the most sense for their local research community and also allows for the greatest productivity in terms of research output. This could include a combination of cost-sharing, cost-reimbursement and reduced or no-charge services for those unable to cover these costs from other sources. Many centers have created "charge backs" for the services provided by the former GCRCs, but this has only led to a shift in costs borne by the CTSA to the other NIH ICs. While this is seen as the only viable approach to sustainability in light of reduced institutional budgets because of cuts in state and other funding, some CTSA researchers believe the use of nursing services and outpatient and inpatient beds is essential to bringing bench discoveries to clinical application. In addition, many entry-level investigators do not have the resources to pay for these services at a time when they need them most for the career development.

Many respondents proposed that NCATS should provide clear expectations to CTSAs about costs to NIH-supported projects, including clear guidance on which CTSA resources will be provided at no-charge vs. partial-charge recovery. This guidance should be discussed with and communicated to all of the NIH ICs so that there is clear understanding and expectation on how much the individual IC-funded research projects are expected to pay for various CTSA services.

Resources for training also were of great concern to many respondents. They stressed the importance and unique value in providing a multidisciplinary, translational environment for trainees. These cut across preclinical and clinical categories and are the key to the long-term success of the entire research enterprise and the future national research enterprise. Respondents believe they are underfunded in the area of training and must turn away many highly qualified, talented applicants with tremendous creative potential. If greater numbers of scientists trained in clinical and translational science disciplines is a desired goal of NCATS, additional funds must be provided, particularly in this time of reduced NIH IC investment. Providing additional training funds for research coordinators and nurses also would be vital for aligning resource allocation with the need for an effective translational research workforce.

In addition to these suggestions, specific requests to be included in the upcoming RFA were proposed:

- Pilot projects to launch junior investigators
- Specific funding for collaborations among CTSA and for national consortia activities
- Informatics to support biomedical research across CTSAs
- Biostatistical and clinical research ethics support for program development and training

- Face-to-face annual meetings
- Funding to develop sustainable community interrelationships and infrastructures, such as academic community partnerships, especially to address health disparities, PBRN, CBPR and capacity building
- Fund NCATS' Bridging Interventional Development Gaps (BrIDGs) program to provide funding to CTSA applicants in efforts to bring therapeutic agents from research lab to clinic
- Fund development of biomarkers and/or other surrogates for efficacy to increase efficiency of translational research
- Acknowledge unique needs and funding opportunity for research on pediatrics, chronic disease and nutrition
- Community engagement programs to help NCATS educate the public about the importance of, and participation in, translational research
- Improvement of CTSA institutions' grants and contracts offices, IRBs, use of electronic health records for research, and use of clinical research space
- Pilot awards programs aimed at new models of cooperative research that lead to early clinical trials of diagnostics and therapeutics, to community engagement

Reducing the Costs and Time Needed for Implementing Large, Multi-Site Clinical Studies

Responses to this question included many of the same issues addressed in response to Question 3. In addition, however, there was a strong sentiment that the conduct of large traditional randomized controlled trials should not be the purpose of the CTSAs, and the CTSAs should not be expected to expend resources for their support due to budget constraints. Rather, CTSA efforts should be directed at finding best practices to reduce the time and effort required for setting up collaborative clinical trials or ways to lower the costs and improve the efficiency of the various clinical research units. CTSAs should be devoted to innovation and testing novel and better methods of conducting clinical research to provide answers to key questions using improved statistical analytical methods or new ways of conducting trials.

Many respondents also suggested that the CTSAs will be best utilized as a means for the ICs to conduct large-scale trials when the ICs initiate the process. Respondents point to the NeuroNEXT model, which could be followed by the other ICs. They suggested the best approach is for the ICs to leverage the CTSAs rather than expect CTSAs to become CROs that will leverage the ICs. However, for these efforts to be successful, there needs to be a steady, predictable stream of studies across the ICs that utilize this infrastructure.

A full-time CRU/CRC with inpatient and outpatient facilities and staff is thought to provide more efficient services than part-time or shared units and is an asset for performing clinical trials. It is critical that NCATS continue to provide support for these units through the CTSA program, especially at sites where the volume of clinical research activities justifies the existence of these units.

Sharing of data was proposed by many respondents as an important approach to reducing time and costs. Shared data from pilot studies, data for recruitment efforts and comparative effectiveness

research and patient reported outcomes are being pooled, for example, by the University Health System Consortium for comparative effectiveness research (using supplemental funding from the University of Chicago CTSA).

Most respondents proposed an interoperable, ontogeny-driven IT infrastructure. A software development company proposed a suite of solutions that included developing a robust medical ontology that controls specialized tools and applications that support translational medicine across the spectrum, from genomics to clinical practice guidelines incorporating personalized medicine. They also proposed a referent tracking system to clearly identify and accurately track a patient's medical issues over time, a system for clinical trial recruitment that aggregates data from multiple sources such as diagnoses, lab results, medications and tissue repository data, and tools to support hypothesis generation and enable researchers to query data and see underlying patterns interactively and in real time. Other respondents stressed the importance of IT going beyond the interoperability of the informatics infrastructures and platforms to include usability of the information content, knowledge creation and knowledge representation processes as drivers of new science in a distributed setting. Data analytic projects should be supported along with training on how to use such resources, technical support, governance and ethical support and a collaboration database to allow CTSAs to identify strengths at other CTSAs for collaboration.

Most respondents are looking for a shared regulatory infrastructure and one respondent suggested empowering a "regulatory leader" to create consortium-wide agreements to facilitate collaboration. This is an important goal, and the CTSA consortium is an ideal platform to implement common tools and agreements that reduce the cost and time to implement multicenter trials. IRB approvals and contract negotiations remain the major sources of delays. Study and reporting of those metrics, with feedback to sites, as has been done by the CTSA Strategic Goal 1 (to build national and clinical research capability) Key Function Committee has already resulted in improved metrics. Development of template contracts, accepted by all participating institutions, as well as IRB reciprocity, such as in the progress CTSA IRB share, will further accelerate trial implementation. The consortium could develop and share other tools for multi-site clinical studies, including protocol and database development tools, such as CTSA-developed prototype (in progress) and REDCap, or a more robust database version when more data elements are required, and database integrated tracking tools for central biospecimen collection. CTSAs are well positioned to continue their progress in this area.

Many CTSA respondents encouraged the use of electronic health records (EHRs) in clinical studies. For example, point-of-care randomization can occur at a health care encounter with minimal interference with standard care where the baseline and outcome data are captured through EHRs. Another suggested the EHR be used to find important safety signals without requirements for huge Phase 4 randomized studies.

While a few respondents propose a mandatory requirement for all CTSAs to agree to a shared regulatory environment, most proposed more middle-ground approaches:

- Streamlined IRB review using a suite of options described in response to Question 6 (Human Subjects Protection) and a common IRB software program that evaluates the various steps of the IRB approval process (i.e., NeuroNEXT)
- Common contracting method
- Central mechanism for regulatory practices in community-based research
- Guidelines and training to establish standards for the conduct of clinical trials that highlight best practices
- Recruitment and enrollment assigned to a specific CTSA core, with sharing of best practices across CTSAs
- Website that contains a library of clinical trials that can be searched by disease and that lists ongoing clinical trials to aid recruitment
- Development and/or use of pediatric networks to enhance recruitment of children of all ages to studies
- Use of community engagement help in the identification of patients with specific illnesses, or rare diseases, through partnerships with patient advocacy organizations and other community organizations on a national scale
- Laboratory and database for biomarkers
- Integrated national molecular screening library to increase repurposing of drugs, EMR, pathways of disease
- National network of core laboratories for CTSAs — for regional access to resources

It was noted that information sharing has been enhanced by the work being done by the CTSA Consortium Coordinating Center at Vanderbilt.

Human Subjects Protection and Bioethics

In the responses to this question, several central themes emerged. Respondents suggested the need for an infrastructure investment to identify and avoid barriers to translational research. Training of investigators/research staff in bioethics will assist in recruiting participants into clinical studies, understanding and enforcing intellectual property issues that block innovation, and implementing new methods for informed consent with research involving, for example, point-of-care randomization or widespread sequencing of healthy subjects' genomes. Principles of ethics must be inserted into the design, recruitment and implementation phases of research.

The Ethics Consultation Working Group (CWG) has played an important role in creating a professional community to share strategies, policies, practices, approaches and information about consultation services. Such services were limited to a handful of institutions, including Hopkins, Stanford and the NIH Clinical Center, in the early 2000s. By March of 2012, 41 CTSAs had established research bioethics consulting services. The Ethics CWG, which currently includes approximately 50 members from 40 CTSA institutions, has established a Web forum and holds quarterly conference calls to discuss ethical issues and to share practice polices. In 2010–2012, the working group received a supplemental award for a data-sharing and standardization project designed to advance two important milestones toward the

long-term goal of creating a system for CTSAs to share research bioethicist data across institutions in a database for research, quality improvement and education.

Greater support of consortium activities (e.g., administrative supplements) that allow key function committees to set consortium priorities would strengthen development and maintenance of networks that provide services, protect human subjects, avoid unnecessary barriers and burdens, and promote public trust. Several respondents supported the importance of biostatistics, epidemiology and research design (BERD) as a key activity, although it is not supported at all CTSA sites, to serve as the conduit for the assistance provided to investigators that leads to extramurally funded studies. Thus, it was recommended that the CTSA program consider BERD expertise in the regulatory and scientific decision-making process as a requirement.

Members of one of the CTSAs and associated junior faculty strongly supported the importance of the CRU. In addition to its many other attributes, a full-time CRU must ensure subject safety by requiring investigators and biostatisticians to conduct detailed review and to provide feedback to all investigators proposing use of the CRUs. In addition, two full-time Research Participant Advocates review all CTSA-supported protocols for safety, provide feedback to study teams, participate in start-up meetings and directly observe the informed consent process in randomly selected studies. The CRU faculty and staff also conduct biannual Research Subject Safety training for investigators and study coordinators. They see this as a model for other CRUs and an important reason to continue full support of CRUs.

Human subjects' protection was seen, not unexpectedly, from the perspective of the Institutional Review Board (IRB) and associated regulations. Most respondents found the IRB process to be burdensome, redundant and not necessarily relevant to the risk posed to the participants. Some form of centralized IRBs is supported by most respondents and holds the promise of improving the efficiency and lowering the cost of clinical research by decreasing duplicative administrative functions. Respondents encourage NCATS to take an active role in supporting central IRBs by NIH-funded institutions and helping to develop guidelines for assessing risk, making exemption determinations and using expedited review. While many support a central IRB approach, others raise concern that reasonable input by the local investigators and community involved in the research being reviewed is necessary to contribute to the ethical analysis of the proposed research.

An important aspect of protecting research participants is assuring that IRB members, chairs, researchers and research teams have an understanding of research ethics, the assessment of research risks and benefits, and strategies for minimizing research risks that is appropriate to their role. Thus, NCATS should support continuous quality improvement in IRB members to ensure they are up to date on new guidelines and practices related to research review and, in particular, to translational research. IRBs that review significant amounts of community-engaged research, for example, are developing innovative research ethics training programs for community partners that align with their educational background, literacy level and research roles rather than requiring them to take the online ethics training course sponsored by the Collaborative Institutional Training Initiative. These should be evaluated, disseminated and able to "count" toward the federal requirement for research ethics

training. These efforts to develop effective mechanisms for regulatory practices in community-engaged research should be supported across the CTSA program.

Along with concerns about the IRB process, respondents requested a protocol template be prepared to enhance the development and submission process. It was pointed out that the CTSA Strategic Goal Committee 1 (SGC1) has addressed process changes relating to protocol development and IRB review by: 1) creating an IRB protocol preparation service; 2) providing investigators with a check sheet that outlines the necessary components that must be addressed in a submitted protocol; and 3) installing and implementing an electronic system for IRB protocol submission. However, until there is a centralized IRB process, improvement of IRB function at local sites is truly the stepping stone to enhancing the efficiency for multi-site studies.

Ultimately, the goal is to streamline the IRB process; therefore, respondents proposed novel solutions to increase IRB efficiency. The strategies for this positive outcome include: 1) creating a system in which a single IRB conducts review on behalf of a consortium of two or more sites (reciprocal deferral); 2) implementing facilitated central IRB review, a process by which a local IRB or representative accepts central IRB review, modifies it, or conducts full review; and 3) establishing an IRB consortium, in which a group of research institutions form a new entity to manage, audit and monitor clinical research, including IRB review. These multiple methods each have benefits and drawbacks. However, the CTSA consortium should be able to apply the appropriate method to meet diverse study needs or to accommodate the institutional requirements of sub-groups within the consortium. The CTSAs are in a unique position to oversee the development of IRB systems that will benefit those planning studies at the NIH as well as investigators at CTSA sites.

Encouraging Shared Investments with Public and Private Funders Both Nonprofit and For-Profit

Investments can be described as financial, resource-sharing or human, which respondents addressed in their response to this and other related questions. In general, respondents supported aligning with industry/pharma to bring academic expertise in innovation, biology and pathogenesis of disease to pharma expertise in formulation and toxicology. They urge NCATS to go beyond pharma/drugs to devices, diagnostics, vaccines, prevention, health care delivery and health services research.

One CTSA respondent pointed out that public funds are generally invested in early stage development with no expectation of financial return on investment; private funders generally expect a profit from the later stages of development. Thus, shared investment may be a misnomer, as investment on the same project at the same stage is not generally achievable. Rather, they advocate a policy for academic centers to carry out the basic studies and early “proof of principle” in the most rigorous and compelling fashion they can and then focus energy on efficiently transferring the best of these discoveries to the private sector for subsequent development.

The response from the consortium of 60 CTSAs enumerated the models that are in evidence today. They described the integrated, national drug repurposing approach supported by Eli Lilly and NIH that

explores existing compounds in high-throughput screening and the advantage of combining that with data from health systems on the known usage of approved drugs in the "real" world. They reference other efforts to explore data for drug repurposing (FDA Rare Disease Repurposing Database). Also, there are a number of models for joint therapeutics development projects with disease advocacy groups. They fully support the integration of academic investigators into the collaborative repurposing efforts and believe it will substantially increase the knowledge base and pool of methodologies available for proof of concept studies.

Active interaction with the FDA is supported. One respondent suggested CTSAs hire executives and scientists from pharma and biotech to direct and staff specialized CTSA centers to help move potential compounds through early stage research and development to IND submission and clinical trials. This would facilitate academic/biotech partnerships and overcome barriers to moving findings through the development pipeline. Another suggested supporting a full-time employee at each CTSA to move science to industry through a centralized office of technology alliances. Others suggested the importance of a Business Development infrastructure that understands the needs and business models used by industry. Some CTSAs have experienced success in this arena and best practices should be shared across the CTSA consortium.

Individual CTSAs report working collaboratively with private funders on projects that benefit both groups, especially in the areas of novel therapies and devices, which enables a university to combine its expertise with a for-profit company's strengths. For example, the CRUs partner with the private sector when industry uses the CRU to conduct its studies. The CTSA consortium, working with public and private funders, both nonprofit and for-profit, in pursuit of common goals, is consonant with the aims of the consortium and potentially valuable in creating resources that will ultimately benefit public health. There are several ways the CTSA consortium can effect such interactions, including providing resources for drug screening, using EHRs and data warehouses to describe responses to existent drugs, identifying patient populations for drug trials (especially for investigations of rare diseases), engaging in comparative effectiveness research, and providing nursing and facility infrastructure for industry-sponsored studies. Other respondents report using social media (e.g., Twitter, Facebook), assessing community public health practices and working closely through community outreach to public and private sponsors of research (e.g., CDC, AHRQ, RWJF, among others). Cataloging CTSA activities in this area could help decision making for NCATS to identify strategic alliances.

Testing drugs and devices in children remains a high priority for both the pharmaceutical industry and the pediatric community. A robust and efficient infrastructure for carrying out this mission is not entirely in place and would be an ideal opportunity for a public-private partnership between the CTSAs and the pharmaceutical and device industry. In addition, pharmaceutical companies have a library of compounds that have been tested in humans but have not produced the desired effect. Some of these compounds may be able to be repurposed for testing and possible use for pediatric and rare conditions. Public-private partnerships will need to be established so that these opportunities can be effectively pursued.

In this time of fiscal constraint and reduction in funding from federal sources, respondents requested that program requirements that limit the ability to integrate funds from multiple sources (e.g.,

institutional funds, private funding, funding from other federal grants) for programs, training and research be reviewed and eliminated. Many CTSAs have been successful in developing partnerships with private entities, profit and nonprofit, who provide resources and support for CTSA efforts. The ability to integrate these funds with CTSA funds would enhance the ability of CTSA to develop and implement innovative partnerships and research. However, some respondents raise the specter of conflict of interest and serving the best interests of the public both in the expenditure of resources and risk/benefit of new therapeutics and warned that NIH should be cognizant of public perception in working with for-profit organizations.

Approaches to assuring accountability and transparency while reducing barriers to innovative uses of funding from multiple sources to implement or expand programs could support further innovation and discovery. Policies must be established that ensure publicly funded research data and findings are publicly accessible and profits generated are shared.

Models for interaction with the community were proposed. The Community-Campus Partnerships for Health has been facilitating the Community-Based Participatory Research Funders Interest Group currently comprised of about 50 public and private funders in the U.S. and Canada, many of whom do not refer to themselves as research funders, per se, but view community-engaged clinical and translational research as a strategy for building healthier communities. The CTSA consortium, having identified priorities through the process referred to above, should aggressively pursue mutually beneficial partnerships with public and private funders in community settings.

The CTSA program should pursue a dialogue between CTSA sites and organizations responsible for public policy decisions. Respondents urge NCATS to engage with the Centers for Medicare and Medicaid Services to co-fund CER, community-engagement and social media approaches to more efficiently and rationally implement medical advances and with the Veterans Administration to learn from their successes and failures. The Key Function Committee, focused on public-private partnerships to enhance collaboration across DHHS agencies that share a mission similar to the CTSA mission (AHRQ, CMS, FDA, CDC, etc.), should work closely with the NIH Public-Private Partnership Program and other initiatives coming out of NIH.

Priorities for Shared Consortial Activities Across the CTSA Sites

The CTSAs, through the Steering Committee and the Strategic Goals Committees, have been developing and prioritizing national goals for the consortium. This process has led to significant progress in some areas (e.g., national guidelines for training and competency in clinical translational research). It is clear to most respondents that the CTSAs and NCATS need to continue to develop, assess and implement shared consortium activities. Funding is a key limiting factor for high-priority consortia activities. It will be very difficult for most CTSAs to allocate additional funds to consortium activities without compromising local support activities that also contribute to translational science.

The Governance System of the CTSA consortium has established that the Steering Committee, through voting, can set the priorities of the CTSA program. However, some respondents are not satisfied with

this approach. There are differences between and among the CTSAs that may make conforming to the priorities impractical or, at times, impossible, including: 1) faculty expertise; 2) the availability of an inpatient Clinical Research Unit; 3) an active and fully developed electronic health record and/or data warehouse; 4) membership in a health research network; 5) capabilities to perform drug toxicity studies, small molecule screening, etc.; 6) genomic and/or proteomic expertise; 7) the availability of specific high-end instrumentation; 8) the number and type of partners for a CTSA site; and 9) location in a metropolitan or rural area.

Many of the responses focused on understanding, measuring and guiding the priorities moving forward. For example, one respondent noted that funding opportunities provided have undergone specific review to determine how useful and productive this targeted and specific funding strategy actually was. Such information, if available, would be very informative in helping to determine how to make future allocations to consortia activity.

Many respondents noted the importance of not conceptualizing the CTSA as an "NIH funded CRO or simply another clinical trials network." Some respondents preferred that a defined set of shared consortium activities be identified, and those CTSA sites that have the capacity to participate in some or all of the proposed shared efforts do so. It is incumbent upon NCATS/NIH and the Steering committee to ensure sites have the "strength" to participate in the priorities and to help those with fewer capabilities to develop them through mentorship, shared resources or additional funding.

Some questions were raised about the continued support of the key functions of the CTSAs and the yet unknown priorities of NCATS. Only after determining which of the key functions deserve continued support and activity will it be possible to establish the strengths of the CTSA sites for the future activities of NCATS. Several respondents commented that diverging from support of the full spectrum of key functions will waste the extensive efforts of the consortium to date and, perhaps most importantly, severely limit the local leverage of the CTSA programs at their home institutions and in their home communities.

Respondents identified specific consortia activities that they would like to see implemented:

- Through NCATS and the CTSA Consortium Executive Committee, rank the priorities of the national Consortium, establish outcomes and milestones, and allocate funds to achieve the milestones and goals. Award supplemental funds for targeted collaborative projects across sites.
- Identify regional or topical groups of CTSA institutions as models for intense and differentiated investment in specific translational goals. Have each CTSA identify its top five strengths, and then network the CTSAs to create functioning groups addressing similar goals.
- Determine the CTSA program's real successes in drug discovery and development, training and retaining translational investigators, improvements in regulatory, informatics, translational methods and technologies and how were they measured.
- Improve sharing of training and education resources, including in nontraditional areas (e.g., biomedical informatics) across the national and regional CTSA consortia.

- Provide for rapid and efficient sharing and adoption of best practices in all areas of clinical and translational research and education across all CTSA program facilitated by the new CTSA Consortium Coordinating Center.
- Promote research on and dissemination of evidenced-based practices to improve maternal and child health with the collaboration of other academic institutions, state agencies, health care providers, insurers/payers, physician and nursing organizations.
- Encourage the ICs to better leverage the CTSAs by providing funding for high-priority, high-impact programs that will be implemented more rapidly and at lower cost through the CTSAs.
- Facilitate improved social networking among and between CTSA investigators, NIH and the community to identify priorities and encourage the sharing of ideas and joint, collaborative research projects.
- Coordinate the work of the Key Function Committees with what is going on at the NIH level. For example, the Public-Private-Partnerships KFC is working on identifying projects in the pre-competitive space that industry partners may have an interest in, but there are ongoing discussions at a higher level about how NIH/NCATS can collaborate with pharma partners. These types of discussions should be coordinated.
- Preserve the capability of the CTSA PIs to leverage other NIH programs and foster the institutional leadership model that has enabled CTSA investments and innovations.
- Re-examine the funding and review processes. Leveraging institutional investments requires alignment of CTSA support with each institution's unique strengths and internal needs. NCRR's funding formula disadvantaged many CTSAs from the outset by limiting funding.
- Integrate all of the CTSA components to carry more impact than the component-by-component scores. This is particularly germane since the CTSA's leverage of other support means that the majority of CTSA components are also being supported by non-CTSA funds.
- Sustain the momentum created by CTSA biomedical informatics to go beyond the interoperability of the informatics infrastructures and platforms to include usability of the information content, knowledge creation and knowledge representation processes as drivers of new science in a distributed setting.

Measuring the Value Added of the CTSA Program for Science, the Translational Mission and Improvement of the Nation's Health

Changes to the health of the public and the impact of a program as new, diverse and large as the CTSA program are difficult to measure both within and outside individual CTSA institutions. Respondents have identified barriers to measuring success and have suggested approaches that might be considered. Many pointed to the ongoing work of the Evaluation Key Function Committee, the Strategic Goal 4 Committee (Improve the Health of our Community and the Nation), the American Evaluation Association and the NIH Office of Program Evaluation in developing logic models for evaluation.

Several respondents noted that since the beginning of the CTSA program, NIH has funded an independent external evaluation that has focused on: 1) the early stage of program implementation;, 2) a process-level assessment (using mixed methods) of short-term outcomes and achievements, including

a publications analysis, interviews with investigators and program staff (a utilization study); and 3) an education and training study.

In response to this question, members of the CTSA consortium proposed developing a logic model to identify short-term, intermediate and long-term goals to reflect progress. The model implies building evaluation into each aspect of the planning and implementation of every project and ensuring that process analysis and barriers and bottlenecks in the research to practice continuum are included. The logic model would detail causal pathways and would generate and test hypotheses about how CTSA efforts contribute to key translation outcomes. For example, one respondent noted that you "can't enroll patients in clinical trials unless there is a long-term positive relationship with community, which in turn depends on building community understanding of clinical research."

Members of the Evaluation KFC noted the external evaluators, in collaboration with a working group of leaders in the Consortium Evaluation KFC, also developed a draft logic model for the CTSA consortium that identified intermediate and long-term objectives. This logic model frames questions for measuring value added from the CTSA program, including impact on health status and health equity. The consortium has intended to continue using external evaluators to examine these intermediate and longer-term outcomes of the collective effort. Thus, the continued funding by NCATS of external, objective program evaluation of the consortium is critical to documenting the contribution of the CTSA program for improving translational science and the health of populations within the nation.

CTSA consortium members proposed using a Coordinating Center supported by a technical system that integrates data sources with process tracking and reporting utilities so that consortium results can be retrieved and reported. Another respondent suggested that the annual reporting of performance metrics should be supported by a monitoring and reporting system designed to collect these metrics. Such a system would provide a controlled data entry environment that ensures high-quality, accurate and complete data submission, enforced through business rules and data integrity constraints. Data collected through the system would be used to generate reports that awardees could use as content in annual reports; provide benchmarking of awardees across the program; and provide NCATS stakeholders and decision makers with data on overall program performance, underperforming projects and major achievements. As with all important endeavors, this requires time, human resources and funding.

Other perspectives emerged from the respondents. Noting that all sites have evaluation functions, respondents supported an effort to define and implement standards for an ongoing formal evaluation process at each site to evaluate activities from basic science to effects on the health of the public. The relationship with STAR METRICS (Science and Technology for America's Reinvestment: Measuring the Effect of Research on Innovation, Competitiveness and Science) needs to be better defined and its value for this purpose explored. Others suggested that BERD serve as the vehicle for constructing measurement and sample schema to address evaluation.

Respondents from one CTSA noted that systems are in place in some states to permit documenting the effects of the CTSA program on population health. These efforts are — by necessity — on a small scale,

bounded by target groups, geography and/or disease, and are built on existing data collection efforts and with funding streams largely outside the CTSAs. The systems present in some states vary but can often allow reasonable evaluation of CTSA program effects on a state-by-state basis, and they could address some measurement issues. The CTSA consortium is in a unique position to partner with these systems and provide the first clear evidence of the positive effects of the program.

Several respondents cautioned about how comparisons were made among CTSA metrics. They felt it was important to compare metrics across CTSAs of like size and funding level, to clarify and institutionalize the multi-level structure for evaluation of the CTSAs (internal units within each CTSA, a national evaluation across the national consortium and as a single integrated entity) and how to identify how this framework can be used to describe typical action scenarios that achieve CTSA objectives.

How and what to measure was also discussed among the respondents. One CTSA respondent proposed developing an agreed-upon set of core descriptive variables that can be used to characterize and summarize the 60 CTSAs (e.g., size, type of location, multi-institutional or single institution, etc.); and identify a small set of key common metrics that enable comparisons across CTSAs. Another pointed out that all results related to a given CTSA's efforts, whether due to direct NIH dollars or institutional funding, should be a part of the measured impact of a given CTSA.

Another respondent suggested focusing the evaluation in the immediate future to individual diseases, specific populations and/or bounded geographic locations is most reasonable and will provide an opportunity to "connect the dots" between CTSA program efforts and changes in health indicators. One respondent supported pre- and post-award trend analyses as the best methods for drawing conclusions about the successes of the CTSA program because confounding factors abound for any observed changes in the scientific landscape and the health of the nation.

Respondents pointed out that the CTSAs have conducted enough diverse pilot projects across the consortium and locally that in-depth analyses can be conducted and used to explore and identify the characteristics of proposed projects that appear to be linked with success in achieving short-term, intermediate and, in some cases, long-term translational outcomes. The CTSA program can take advantage of this sample of innovative, potentially ground-breaking pilot research projects to better understand how to facilitate the process of translational research.

Specific items to be measured proposed by the responses include the following intermediate outcomes:

- Increase in number of grants received
- Increase in number of publications in peer reviewed journals
- Increase in number of protocols submitted to IRB
- Decrease in IRB approval time
- Number of M.D.s/other health professionals taking institute sponsored training
- Changes in academic involvement in translational research
- Number of NIH investigators/ICs that receive direct support for their studies that increase efficiency and reduce cost

- Current translational research projects:
  - Number of unique PIs
  - Number of active protocols
  - Number of IND/IDE submitted/approved
  - Investigator-initiated protocols
  - Interns in the community
  - Community residents referred to medical or social services
  - Number of underrepresented people enrolled in studies

Long-term outcomes might include:

- Increased utilization of new treatments in the community
- Community health indicators improvement

Many respondents commented on the measurement of the value of the CTSA in its relationship to the community. They proposed obtaining input from community representatives on the impact of CTSA through surveys, questionnaires and interviews. They suggested developing case studies illustrative of the inroads the CTSA has made in gaining cooperation, collaboration and success in community settings. Funding would be needed to support this work to measure the effectiveness and efficacy of community-engaged interventions. It would be important to have dedicated staff and infrastructure that relate to and support CTSAs working in the T3 (translation to practice) end of the translational spectrum.

A group of community-oriented respondents recommended that a participatory evaluation be undertaken in which CTSA leadership, faculty, students, community partners, funders and other key stakeholders collaboratively define the indicators, metrics and methods used. There are a number of existing assessment frameworks and tools that could be built upon for this purpose, including, for example, those developed by the CDC Prevention Research Centers Program and the NIEHS Partnerships for Environmental Public Health Program.

Respondents representing the pediatric community supported the measurement and reporting of the number of children recruited into clinical trials, along with their ethnicity, race and gender. In addition, age categories should be developed and reported for children to ensure that all developmental stages are represented. The number of new therapies extended into the pediatric population and changes in emergency room visits for specific diseases (e.g., asthma) should also be measured. Collaborations between child health researchers and their adult-focused counterparts should be counted, and the number of lifecycle studies and the children included in them should be determined.

Several respondents suggested that funds should be allocated to improve the public's awareness (e.g., marketing) of the mission of NCATS and the role of the CTSAs with respect to translational and clinical research. They propose using the CTSAs to emphasize that NCATS has a major role at the local level in promoting research and education, helping specific population groups, and improving the health of the nation (i.e., promoting local agendas in addition to the national agenda). One respondent noted that due to direct support by CTSA to studies of investigators that were themselves supported by over $155 million of federal grant funds for that research, there was a reduction in the needed IC budget; NIH ICs

probably are unaware of this cost savings. Thus, methodology needs to be developed and communicated to NIH IC directors, Congress, the White House and the public to show the value of leveraging CTSA resources in order to prevent duplicative and wasteful rebuilding or research infrastructure for every translational research project that is undertaken.

One CTSA respondent commented on "return on investment" from the CTSA program, noting greater efficiencies in the conduct of clinical trial research including more efficient management of clinical research units, better systems to disseminate information on research resources and enabling technology availability such as high-throughput screening and next generation sequencing, improved and streamlined regulatory processes in human subjects protection, subject recruitment and clinical trials contracting, and dissemination of best practices for conducting community-based research, to name just a few areas.

Summary

Many thoughtful responses were received, and the responses generally demonstrated strong support for the CTSA program. Many respondents expressed strong agreement with the general recommendations made by the NIH CTSA/NCATS Integration Working Group, particularly the importance of enhancing consortia activities and the need to enable greater flexibility for CTSAs to develop local and institutional strengths. Respondents suggested that NCATS increase its efforts to create incentives and leverage CTSA funding by strengthening partnerships with the other NIH ICs.

Communication and the need for transparency also were central themes in the respondents' suggestions. Enhancing communication between and among various stakeholders was considered paramount to the success of the CTSA program. Respondents expressed the need for NCATS to take an active role in providing incentives — both financial and structural — for more openness and better communication.

Although the value of local flexibility was generally acknowledged, discussion of barriers to translational research often focused on the need for central or standardized regulatory, contractual and informatics capabilities. The need for mechanisms to improve efficiencies and decrease time and cost in getting studies approved and implemented was a central concern of many respondents. NCATS was urged to make appropriate infrastructure investments and establish priorities for shared consortia activities.

The importance of community and patient engagement was a theme noted by many respondents, including those from academic and health care institutions as well as community, advocacy and commercial organizations. Improving the health of the public, an ultimate goal, is highly dependent upon broader public understanding of the value and importance of clinical research. Respondents recommended broader efforts to engage community-based practitioners, community-based organizations and the general public through training, relationship building and participation in research.

Funding was a major concern for the respondents. Some respondents asked for not only increased funding for study implementation but also redistribution of funds based on objective measures rather than historical ones. Some respondents expressed concern that focus on discovery or early translational research could drain resources from clinical and community research, while others advocated for strengthening preclinical and early stage translational investments.

The CTSA program continues to be a work in progress. The respondents clearly reflected their commitment to the success of the program and its contribution to building stronger translational research. They showed a willingness to work with each other and NCATS to refine the structure and organization of the CTSA program and the science of translational research. The responses are being carefully considered by NCATS staff as they prepare the next CTSA Funding Opportunity Announcement and continue to look for new and innovative ways to improve the program.[1]

[1] NCATS acknowledges Palladian Partners, Inc., and its sister company, KAI Research, Inc., both Altarum companies, for collecting and synthesizing the results from the RFI.

Appendix A: Respondents to CTSA RFI: Enhancing the CTSA Program

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