Preparedness of the CTSA's Structural and Scientific Assets to Support the Mission of the National Center for Advancing Translational Sciences (NCATS)

CTSA Principal Investigators*

Abstract

The formation of the National Center for Advancing Translational Sciences (NCATS) brings new promise for moving basic science discoveries to clinical practice, ultimately improving the health of the nation. The Clinical and Translational Science Award (CTSA) sites, now housed with NCATS, are organized and prepared to support in this endeavor. The CTSAs provide a foundation for capitalizing on such promise through provision of a disease-agnostic infrastructure devoted to clinical and translational (C&T) science, maintenance of training programs designed for C&T investigators of the future, by incentivizing institutional reorganization and by cultivating institutional support. Clin Trans Sci 2012; Volume 5: 121–129

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Introduction

On December 23, 2011, President Obama signed the Consolidated Appropriations Act, 2012[1] that included the establishment of a new National Institutes of Health center, the National Center for Advancing Translational Sciences (NCATS), with a budget of $576.5 million.[2] The new center will speed movement of discoveries from lab to patients and identify and overcome hurdles that slow the development of effective treatments and cures.[3] These are not new goals; however, the bold move to form a new center, to dissolve another and to reorganize its various components to drive synergies is a rare, if not unprecedented, occurrence. Already, it is causing government officials, scientists, and the lay public to pay attention. The largest single component of the new center will be the extant Clinical and Translational Science Award (CTSA) program, housed within the Division of Clinical Innovation and funded at approximately $487.8 million.[4] Each individual CTSA has been developing infrastructure for the very transformation that NCATS will propel. The first 5 years of the CTSA consortium can be characterized as an emergent, reengineering process, during which institutions ramped up their capabilities and research organizations were incrementally added to achieve critical mass (now 60 sites, see the Appendix). The consortium—what could be called "version 1.0"—was developed within a strategic framework wherein the broadest constituencies of translational sciences were empowered and engaged. A significant achievement has been the establishment and strengthening of the internal connections within this network—between individual scientists, across disciplines, and among academic organizations. As a consortium, we are now positioned to produce transformational change in translational sciences within the evolving NCATS, in what could be called "CTSA 2.0." In this commentary, we describe the pertinent ways in which CTSAs are structured and briefly define a path to support the NCATS's mission and the common vision of improved societal health.

The Organization and Emphasis of CTSAs

A full spectrum of translational science

Basic science discoveries feed the pipeline for translational and clinical research that seeks to move discoveries into practice and policy to improve health. Establishing the efficacy of a new drug, biologic, device, diagnostic, or preventative intervention through clinical research in controlled experimental settings creates preliminary evidence for application to clinical practice. Although the establishment of safety and efficacy is requisite to availability of new therapies, proof of real-world safety, and effectiveness is equally vital to actually affect health. We believe that CTSAs must support all of these stages if we are to systematically improve health; therefore, CTSAs, in the aggregate, cover the entire spectrum of translational science. Importantly, the process by which translational science occurs requires an institutional framework entailing familiarity with all stages, and as such, the "science of translation" has become a fundamental focus and principle of the CTSAs. Wisely, in authorizing NCATS, Congress encouraged the new Center "study steps in the therapeutics development and implementation process…to identify bottlenecks…that are amenable to re-engineering, and develop new technologies and innovative methods for streamlining the process."[5] The large number of clinical and translational (C&T) studies supported or conducted under the auspices of the CTSA programs provides a platform for process analyses that, working with operations experts, address this deficiency and holds promise for ways to reengineer processes.[6]

A disease-agnostic approach to providing infrastructure

As scientists we can understand the notion that infrastructure is not always the most alluring topic. But as CTSA Principal Investigators and institutional leaders, we have begun to see the immense importance in the creation of a resource/program/service that: (1) works across disease areas, (2) does not have to be recreated, and (3) fuels scientific innovation by its very existence. The nature of our operations in creating broad, reusable infrastructure is one of the most prominent symbols of what we do. There is a proxy for measuring the extent to which we perform well: grant funding obtained from NIH's categorical institutes and centers (I/Cs). CTSA support systems (some described here) positively impacts the diverse research funded by the NIH Institutes, Centers, and Offices. Indeed, in the most recently reported project period, the CTSA program supported the research activities of 5,886 unique NIH grants (*Figure 1*). Moreover, the support provided often reduces costs for the services

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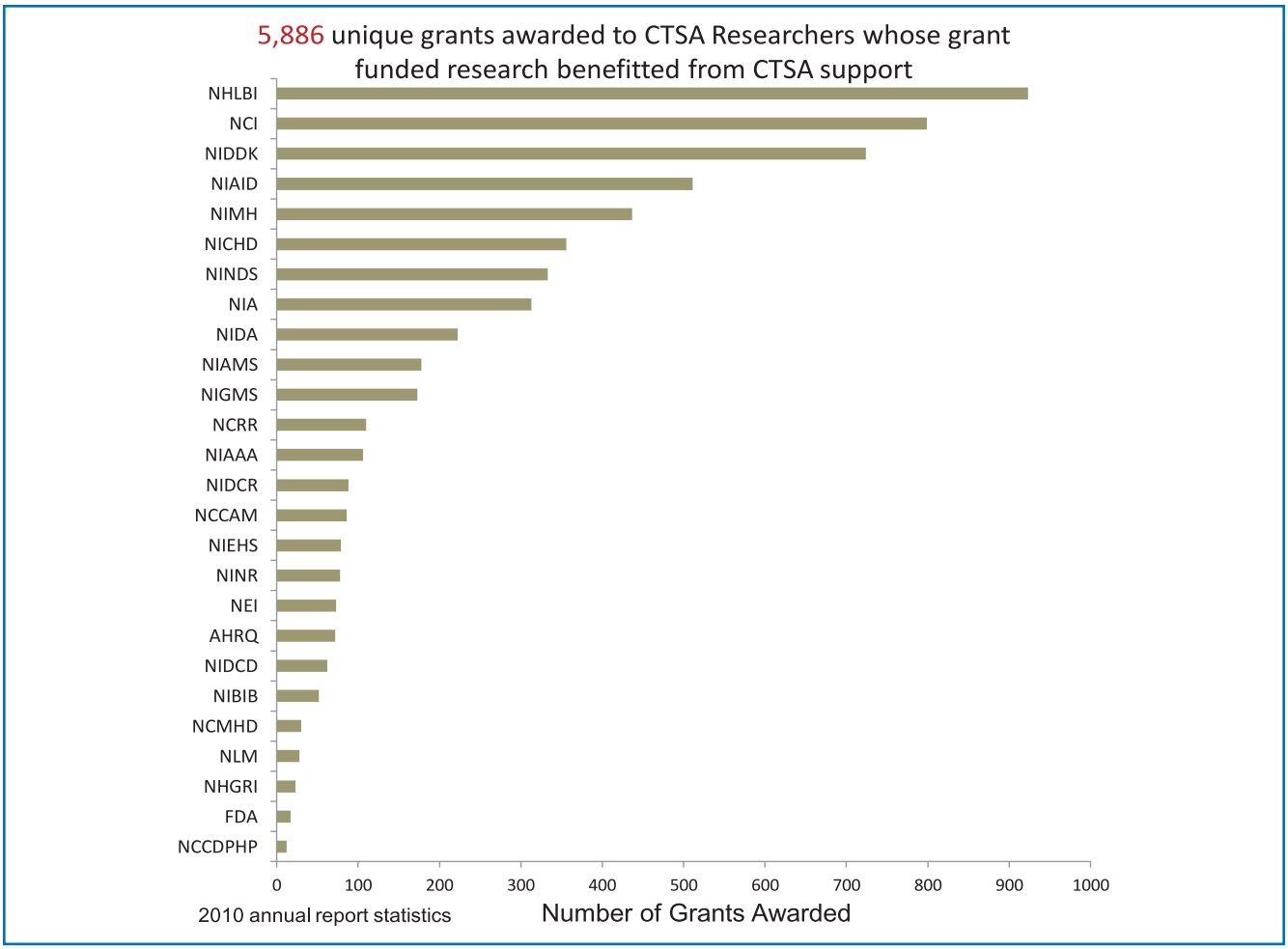

Figure 1. Federal grants that benefited from the CTSA grant resources for investigators whose research was aided by the resources of the CTSA (as reported in site specific annual progress reports, 2010).

offered, extending the purchase power of the NIH funding. CTSA support is supplemented by considerable institutional matching. That Deans and CEOs are willing to co-invest (substantially, in most cases) in this infrastructure is yet additional evidence of the perceived benefits of the CTSA model.

Supporting investigators in early-stage, hypothesis-driven pilot studies

Allocation of pilot funds is an imperative function of the CTSAs to jumpstart innovative science. All sites support pilot and collaborative studies that allow clinical and translational trainees or researchers to generate preliminary data for submission of grant applications, and/or are intended to develop innovative methods and technologies and new collaborations. Local CTSA pilot support of health-related research provides for rapid funding that is typically not available through other sources and is essential to investigators who need to generate preliminary data. These programs are designed to be flexible and responsive to changing opportunities in the field by providing unique resources and fostering new investigative talent in different disease domains. CTSA sites follow accepted standards of rigorous scientific review. Scientific review of the proposed health-related research is handled by faculty who are knowledgeable in the various disciplines and methodologies related to the scientific areas of the applicants. This distributed model for funding pilot studies using CTSA and matching institutional support provides small-scale and early-stage funding. Approximately, 2,000 pilot studies were conducted across CTSAs in the last reporting year (*Figure 2*), greatly enhancing the resultant quality of preliminary data and simultaneously derisking subsequent submissions to NIH and other federal funding agencies. It also represents a flexible infrastructure for locally offered RFAs that can reflect NIH priorities.

Regulatory support

The CTSA consortium has served an active role in not only providing research-focused support for regulatory compliance and management, but in greatly streamlining processes at the institutional level. Spurred by nationwide comparative studies of protocol processing times, many CTSA sites have measurably reduced the length of time for Institutional Review Board protocol review and approval, as well as contract negotiations and final agreements. Development of IRB consortia has emerged, providing multiple-site, single IRB research networks. Many CTSA sites are also implementing an Office for Human Research Protections-approved, collaborative IRB review model supported by an electronic sharing resource. Also, consistent with the NCATS mission of advancing the underpinning methods of translational science, CTSAs are contributing novel approaches to clinical trial

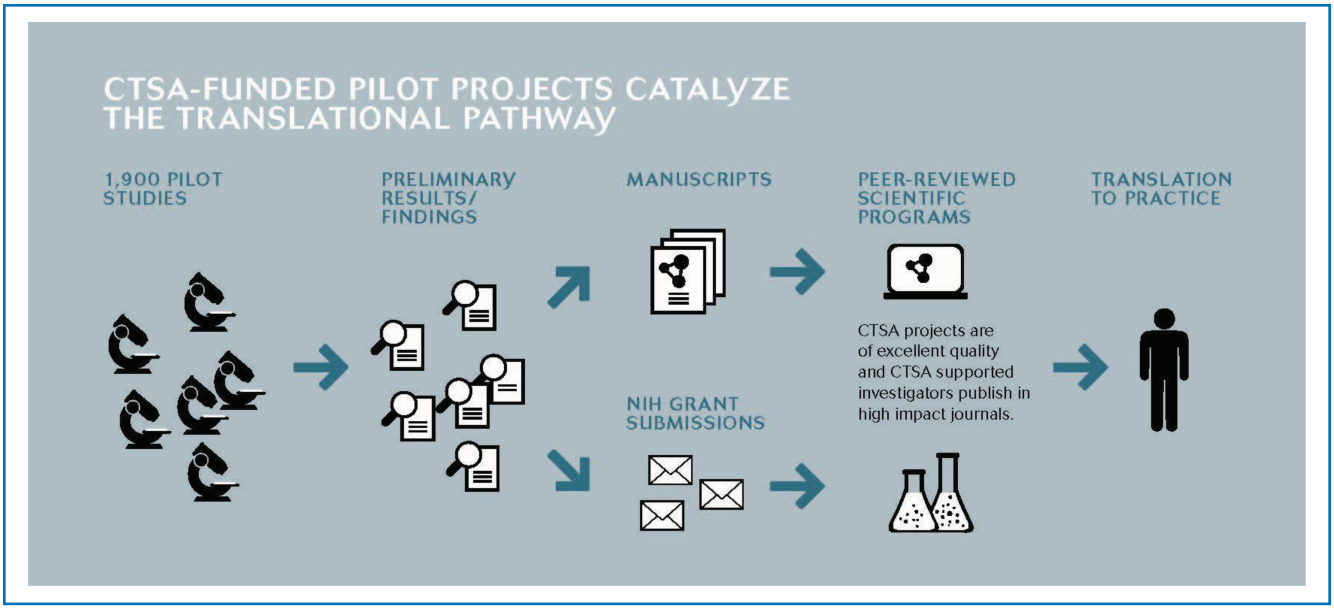

Figure 2. Pilot programs are supported at every CTSA; these programs stimulate essential, small-scale scientific investigation.

design (such as N-of-1 and innovative adaptive designs), conduct, and analysis that interface with the regulatory requirements in ways that will enhance translation of new treatments into use. In addition, every CTSA provides research participant advocacy functions which work with investigators, trainees, and research teams to promote and facilitate the safe and ethical conduct of human research.

Participant recruitment

Recruitment and retention has become a predominant concern due to recognition that failure to enroll any subject is not rare in clinical studies, and failure to recruit the target number of subjects is common.[7] As one example of a tool to help in recruiting volunteers, the CTSA-supported ResearchMatch is a disease-neutral, institution-neutral, Web-based research matching service. Without significant publicity and no advertising, 20,000 registrants have volunteered (and simultaneously learned more about how they can help advance science as participants) and ResearchMatch already serves approximately 1,000 researchers *regardless of disease focus*.[8] CTSAs are also starting to use an i2b2 or other electronic medical record (EMR)-based systems to establish protocol cohort development at given sites to document the adequacy of patient populations (e.g., rapidly quantify numbers of subjects with specific diseases). At several CTSA sites, these and other strategies have resulted in an increase from 60% to 125% in the target subject accrual rate for clinical trials.[9]

Sustaining the Enterprise: Educating and Training Scientists in C&T Research

The CTSAs are ensuring that our nation will have a full pipeline of investigators who have the comprehensive skills needed to continue to bring novel therapies, diagnostics, and preventives to the public, and are able to work across the translational research continuum. The program supports multiple educational initiatives including in most institutions a Master's degree in clinical and translational research and two types of formal clinical research training awards, the TL1 and KL2. There were 485 scholars and 445 trainees reported in 2010. TL1 awards offer medical, predoctoral, and postdoctoral student trainees an introduction to clinical and translational research. In the KL2 program, scholars who already have MD, PhD, or other health-related degrees and who are joining the faculty of academic institutions may pursue additional training expertise and obtain either a master's or doctoral level degree pertinent to clinical and translational research. The didactic elements of these programs are complemented with full-time laboratory or clinically based research. The consortium has also developed and dispersed a comprehensive set of 14 core competencies (*Figure 3*) needed to initiate a successful career in C&T research.[10] In addition, a Virtual University portal houses educational content on courses, competencies, and best practices shared by the consortium and open to the research training community at large.[11] Training in mentoring of trainees and junior scientists, and dissemination of best practices for mentoring are incorporated into CTSA programs. Each CTSA institution offers pilot project research funding to young investigators on a competitive basis enabling trainees and scholars the opportunity to generate preliminary data.

Networked Assets and Shared Tools

Dedicated clinical research facilities

The strong emphasis being placed by NCATS to catalyze the development of novel diagnostic, therapeutic, or preventative approaches will bring with it a requirement for specialized infrastructure and expertise to conduct complex studies ("first-in-humans" studies) under two contexts. First, the successful development of novel therapeutic approaches at some point requires first-in-human testing. This step in translation requires specialized, controlled settings that have the capabilities to generate high-quality research data and assure participant safety in the event of adverse events. Second, translation of important mechanistic insights from preclinical models to validation in humans often requires complex testing of the type that cannot be

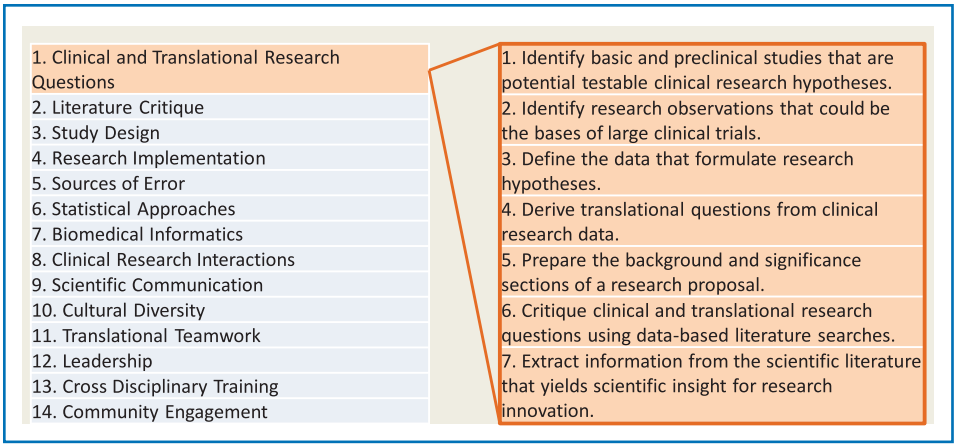

Figure 3. The consortium has developed and dispersed a comprehensive set of 14 core competencies needed to initiate a successful career in C&T research (left) with an example of the subtopics for one competency provided (right).

done safely and with high quality in standard clinical facilities, and requires specialized facilities and expertise. The nation's clinical research centers (CRCs, funded by NCATS and housed within the CTSAs) have been designed with these two components in mind, and provide nursing care, space, and dedicated facilities that support the conduct of inpatient, outpatient, and community-based research. The 625+ inpatient beds and the 800+ outpatient facilities available throughout the CTSAs represent a virtual research hospital, geographically dispersed to serve patients where they live. The outpatient facilities are inherently convenient research sites in close proximity to large, diverse patient populations. In addition, a coordinated core laboratory system is often available, providing centralized, research-grade blood and urine testing, radiological studies, genomic, proteomic, and metabolomic studies, and many other offerings. Nationally, CRCs conduct a vibrant portfolio of advanced, mechanistic patient-oriented research and a full range of human research studies encompassing multiple therapeutic modalities at every stage of the process of product development, from new target identification to discovery through phase 1 studies, and beyond. Pharmacokinetic/pharmacodynamic (PK/PD) studies which require precise timing of drug administration, blood draws and processing, and constant monitoring for the highest standard of safety, are a particular strength; many could not be conducted without the CRC, including studies sponsored by categorical NIH I/Cs. CRCs are also positioned to aid in drug repurposing, a stated priority of NCATS.

Rare diseases translational research

The CTSA facilities are especially critical to research aimed at finding the cause and cure of rare diseases since by their very nature rare disease investigations often require multiinstitutional participation in order to recruit adequately. Although we estimate that there are about 7,000 individual rare diseases, the number recognized grows by 1–2 per week.[12] Approximately, 30 million Americans have a rare disease. Elucidation of the genetic bases of these diseases can provide targets for drug discovery, which may help the patient with a rare disease, but also informs the discovery process for more common diseases, elucidating elements of the biological networks disrupted in these conditions. All the capabilities of the CTSAs, from bench to bedside, from genomics to drug discovery, and from phase 1 to therapeutic trials, can be readily applied to understanding the pathogenesis of rare diseases and developing diagnostic and therapeutic approaches to their management. Furthermore, given the scope of the CTSA consortium, the network renders feasible the conduct of definitive clinical trials, even in "rare" disorders such as those in the Rare Disease Clinical Research Consortia of the Office of Rare Diseases Research. The CTSAs currently support most of the 60 clinical trials of the 18 Rare Disease Clinical Research Consortia of the Office of Rare Diseases Research aimed at elucidating the pathophysiology and treatment of rare diseases.

Human assets

Dr. Francis Collins has noted that opportunities abound to leverage adaptive trial designs.[13] Yet, complex sequential or adaptive clinical trial designs require specialized statistical knowledge. It is particularly difficult when using novel experimental designs to conduct simulation work necessary to develop an optimal design to address a specific experimental hypothesis, the relevant experience will therefore never reside in one place for every study type. However, collective expertise exists throughout the CTSA consortium. The Biostatistics Epidemiology and Research Design committee forms a unique network of biostatistical experts with expertise in the design of complex experiments, flexible adaptive design, and nonstandard analytic approaches tailored to specific translational and clinical technologies. These individuals develop new methods and apply them to real studies, including adaptations to existing methods, such as extensions to the sequential parallel comparison design (SPCD)[14] intended to reduce the problem of the strong placebo response while minimizing overall study time and sample size. Many other human assets (Investigational New Drug experts, Data Safety Monitoring Boards, etc.) exist throughout the consortium.

Capturing and managing data

Data management tools for the support of diverse clinical trials have been adopted or created throughout the CTSA consortium, including REDCap, OnCore CRM software, and Velos eResearch. The development and implementation of electronic tools to enable interinstitutional data exchange and collaborations between investigators at multiple institutions has supported collaborative research across the CTSA consortium. For example, REDCap is an easy-to-use, *freely available* tool for clinical study management and data capture that has been adopted at over 300 academic and non-profit institutions and is now serving 39,000 users. The entire REDCap program has been translated into multiple languages, enabling its use worldwide.[15]

Collaboration tools to enable multisite translational science

Finding experts, specialized equipment or other resources within even *a single* academic medical center can be a formidable task. Rapid identification of scientific experts can inform identification of collaborators, assembling of scientific teams, and matching mentors with junior faculty members and trainees. Many CTSA institutions

have developed and/or adopted systems related to profiling faculty and staff members. Notable examples include: (1) VIVO, an open source semantic Web application used by an international network of institutions to collect and share information about researcher interests, expertise, publications, and grants[16]; (2) Profiles Research Networking software, a similar platform for collecting and storing researcher profile information with a rich network analysis and data visualization user interface[17]; and (3) SciVal Experts, a commercial expertise profiling and research networking tool featuring automated extraction and packaging of data from NIH Reporter and Scopus.[18] The Direct2Experts project was launched in 2011 as a proof-of-concept federation project, compiling researcher profile data from 28 universities for use in a single software user interface.[19] Similarly, the biostatistics committee's CTSpedia.org wiki is a research methodology and research ethics resource containing a wealth of material including how to do reproducible research, statistical graphics, analysis, and design.[20]

The Ability to Conduct Real-World Investigation

Under its authorizing statute, NCATS may develop and provide infrastructure and resources for all phases of clinical trials research and provide direct support for clinical trials through the end of phase IIa. CTSAs have made significant contributions to biomedical research by providing the support and infrastructure for clinical studies from early stage phase I toxicology studies to community-based and comparative effectiveness research (CER). This infrastructure support has accelerated the translation of diagnostic, therapeutic, and prognostic discoveries to clinical application. Community engagement (CE) and comparative effectiveness provide essential insight to establishing the true overall impact of a new therapy under real-world conditions; that is, after drugs have received marketing approval.

Comparative effectiveness research

CER tests not only real-world efficacy of new versus established treatment but also the relative utility and cost-effectiveness of competing preventive, diagnostic, therapeutic, surgical, and behavioral strategies in use. CTSAs have established the infrastructure and personnel (such as health services researchers, implementation scientists, and epidemiologists, within and outside our medical schools) to facilitate these evaluations. Data show that people—and that is *all* people, of any race, gender, socioeconomic level, or insurance status—receive only half of recommended care.[21] Similarly, patients only receive approximately 60% of recommended pharmacologic care.[22] Thus, on average, a drug with 100% efficacy (of which there are very few) could only have an "applied efficacy" of 60% in a real-world setting. We recognize that actually getting people to take medications would not be the central mission of NCATS; however, given the important population health change that would occur with small medication adherence gains, through investigation we can determine the reasons for poor adherence to treatments and determine what infrastructure changes are needed to promote acceptance of new, and older, therapies. This is a task of the CTSAs. Further, the development of CER capitalizes on the public's investment (via taxes and drug prices) in developing new therapies by increasing the likelihood of turning them into actual health improvements.

Community engagement

Social and environmental factors[23] impinge directly and heavily on the health of Americans and so we must understand community and social factors as determinants of health. The CTSAs, through their CE cores, have built bridges between the public and the increasingly complex translational research community. The community is well positioned to identify the hierarchy of unmet medical needs that must be addressed by research. CTSAs have established community research advisory boards, community research education programs, relationships with practice-based research networks (PBRNs), registries of patients and volunteers, and have supported the ability of community-based physicians to obtain and record information necessary for research that reflects real-world performance on new therapies and interventions. The CTSA's potential to use advances in informatics, and to integrate expertise in genomics, epigenomics, and metabolomics into such studies promises to give novel mechanistic insights into how these sociocultural variables modulate behavior and response to therapeutics.

Shared data infrastructure

CTSAs are developing electronic methodologies of data collection from diverse sources, data collation and verification, and sharing of information, as well as newer computational and statistical approaches to handling large, nonuniform data sets. These opportunities will be enhanced by the deployment of electronic health records to primary care practices nationwide, and establishment of health information exchanges to pull data from those practices in a secure and HIPAA compliant fashion. We believe a sizeable proportion of the 100 Initial Priority Topics for CER issued by IOM[24] would benefit from combined EMR-based data analyses.Author: Please provide the expanded form of HIPAA and IOM. What other creative and transformational ways can EMR data be used? We could, for example, develop analytical approaches for leveraging real-world data to assess drug safety, including the particular issue of drug combinations that are common in practice but rarely formally addressed in randomized trials. The advent of "meaningful use" should make shared data infrastructure even more appealing[25] and already there are federal efforts aimed at progress in this domain, particularly in the area of adverse events.[26,27] Elucidation of the genetic bases of rare drug responses is also a key national initiative and can lead to more efficient clinical trials.[28] The CTSAs offer biomedical informatics, pharmacological and epidemiologic expertise, among other key disciplines, as well as a network of 60 centers incentivized to resolve challenges.

A discipline for regulatory science

CTSAs foster the emergence of regulatory science in academia,[29] which is critical to the mission of NCATS and has recently been the subject of an IOM workshop.[30] The need for a strong workforce trained in the arena of regulatory science and the importance of regulatory science as an essential field of biomedical research enterprise[31] is unambiguous. Based on inclusive organizational structure, the CTSAs are quite possibly the only national entities that contain the breadth of disciplinary components (over 40 listed in the IOM workshop publication) required to determine the impact of rules and laws governing FDA-regulated research. Perhaps the T1–T4 subdivision of translational science can be used to create a parallel subdivision encompassing preclinical evaluation of safety and efficacy, clinical trial design and analysis, postmarketing review of safety and optimal utilization, and health policies, including social aspects of regulatory science.

Future Directions as We Move to NCATS

Leveraging strengths

A consortial approach to leveraging human and infrastructural assets will be enabled by the CTSA's informatics tools that accommodate sharing of heterogeneous data, an array of EMRs as a powerful network resource for C&T studies, the innovative services and expertise created by CTSA 1.0, the CTSA's capacity for sophisticated first-in-human studies, and our ability to streamline regulatory processes, enhance commercialization of new discoveries, build biobanks, form collaborations with offices of technology transfer, and more. We have created new models of CEthat could truly accelerate the translation of research into health care. All of these assets present an ideal platform for development of therapeutics and diagnostics, primary prevention studies, networked clinical trials, CER, and studies of emergent public health needs (e.g., H1N1 influenza vaccine efficacy). Many CTSAs represent a microconsortium of regional institutions beyond the primary award site. In this manner, we have become organized with 60 CTSAs as nodes, with regional clusters of institutions around each CTSA, facilitated by a coordinating center, to provide a national infrastructure for CTS.

Working with NIH partners

A key feature of NCATS will be new creative, formal, transparent mechanisms for interaction of CTSA 2.0 with NIH I/C's. Strong, practical partnerships with I/Cs will be essential if the CTSA is to synergize with other NCATS programs, tackle tough scientific questions and challenge areas, and address discovery and development in pediatric and older populations, and in minority communities. These partnerships are being initiated now. Working efficiently *within* NCATS will also be a main priority. For example, there is a national interest, due to inherent cost and time efficiency, in drug rescue and repurposing initiatives.[32] The compounds categorized and available through the Chemical Genomics Center Pharmaceutical Collection[33] effort are likely to be maintained by the NCATS Division of Preclinical Innovation. CTSAs are in the process of complementing these initiatives by providing inpatient and outpatient clinical trials resources supported by high-quality infrastructure, advanced methods, accelerated IRB review processes, and readily identifiable basic and clinical domain expertise. These resources greatly enhance the capability to pursue the discovery, development and application of novel therapeutics, devices, and diagnostics. We also hope to help develop collaborative efforts with the new Cures Acceleration Network as it takes shape.

Human capital

Perhaps the most critical element of our mission is human capital. The integration of many diverse talents is critical to the successful discovery, development, and adoption of a novel therapeutic. Across the spectrum of this endeavor are many established specialties that are well represented within CTSAs and supported by their training programs. These include traditional basic sciences and clinical disciplines, clinical epidemiology, and health services research. However, a stepchild within the "big tent" of clinical and translational research that spans the translational divide—so called T1 research. This catalytic endeavor not only lacks a name but with the erosion of clinical pharmacology as an academic discipline over the past 20 years a critical deficiency in human capital has emerged.[34] NCATS, based on the Science Management Review Board report on Translational Medicine and Therapeutics (TMAT), might foster the development of this discipline by incentivizing use of existing training systems within CTSAs. It might motivate the development of sustainable career structures in translational science in the recognition that many graduates would return to traditional disciplines better equipped to pursue this aspect of CTS within academia or move on to careers in the pharmaceutical, biotech and venture industries, or in the FDA.[35] Training and education in emerging disciplines such as TMAT and Regulatory Science will provide a crucial practical and intellectual substrate for what NCATS seeks to achieve.

Partnerships between public and private organizations

It is undisputed that innovative solutions are required to address the translational valley of death, the steepening patent cliff,[36] and the lack of therapeutic agents being approved despite increased industry investments.[37] During this time, the cost of this endeavor has risen dramatically, reflecting primarily the increasing cost of failure. Indeed, the number of new drugs approved each year has remained roughly constant for *over 50 years*.[38] Proposals to shake up the status quo are arising, including crowd sourcing,[39] open access models, various public–private partnerships, precompetitive collaboration,[40] venture philanthropy,[41] industry investment (e.g., Global Centers for Therapeutic Innovation[42]) and even prizes for solving development challenges.[43] All seem worthwhile. The CTSA programs, housed within leading academic medical centers, are poised to take responsibility for the portions of the translational process that we can solve, and to take action when new, proven methods arise.

New target discovery, lead identification, proof of mechanism studies in both animal models and in humans, and the related intellectual property licensing to the private sector, are critical steps on the path to bringing new therapies to the public. CTSA institutions now collaborate with their respective offices of technology transfer and licensing. Half of CTSA sites have created formalized novel programs with technology accelerators, innovation incubators, and commercialization facilitation. The CTSA's Intellectual Property portal is a Web-based, open access IP search tool that aggregates and promotes technologies from CTSA sites in order to stimulate collaborative research activity by encouraging the formation of new public–private partnerships.[44] Similarly, the Pharmaceutical Assets Portal is a tool that provides academic researchers access to potential small molecules that may be available for repurposing within industry,[45] whereas *i2i connect* is a consortium tool that connects academic inventors with device and biotechnology companies.[46] Another example is the Patient Impact Initiative, a collaboration between CTSA sites and Partnership for Cures, a nonprofit foundation focused on rediscovery research.[47] The consortium has developed a package of sharable competencies for drug and device development focused on the ability to develop new drugs, manage the regulatory process, recruit collaborating investigators, design clinical trial protocols, prepare budgets and contracts, address IRB requirements, perform data safety monitoring, and execute business models to bring a new drug or device to market.

Measurement

An ongoing challenge of large-scale, complex organizations such as NCATS and the CTSA Consortium is to set in place metrics of success that effectively assess the impact of clinical and translational research and thereby guide biomedical science

and health care policies at the national level. The CTSAs have now created the infrastructure to: (1) facilitate clinical trials designed to test new diagnostics and therapeutics discoveries and (2) determine how best to bring health improvement innovations to the public. Now we need to measure the real-world impact of these new interventions. This is a daunting challenge; however, our all-encompassing pursuit is to be a network of action rather than soliloquy. We will make practical, noticeable progress on this front, including embracing any NIH-driven metrics.[48]

Conclusion

To prepare for CTSA 2.0, we will complete a cataloging of resources from across the Consortium, including those that can be deployed for the discovery, development, and transfer to the private sector of novel therapeutics, diagnostics, and devices. We will support the training and career development of investigators across the spectrum of clinical and translational research. We will identify novel approaches to enhance the skills of C&T teams for developing new therapeutics, diagnostics, devices, preventatives, and CER strategies. A framework for prioritizing IT and Informatics goals will be established, including methods for utilization of EMRs, integration of such information with diverse data sets emerging from translational studies, and harmonization of data elements across sites and networks to enable reuse. The CTSAs will also develop systems to ensure effective communication between research and community networks, as well as tools to support new methodologies in CER. In the short time that the CTSA program has been fully in existence, we have become an agile national consortium of 60 sites dedicated to the advancement of translational science that is truly transdisciplinary and functions at multiple levels. We remain deeply committed to the mission of NCATS and are prepared to respond organizationally and scientifically to any initiatives arising from NCATS.

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