Association of
American Medical Colleges
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0400 F 202 828 1125
www.aamc.org

October 25, 2019

National Center for Advancing Translational Sciences
National Institutes of Health
6701 Democracy Blvd, Room 9113, MSC 4874
Bethesda, MD 20892

Re: Request for Information (RFI): Enhancing the Clinical and Translational Science Awards (CTSA) Program (NIH NOT-TR-19-027)

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment on the NIH's National Center for Advancing Translational Sciences (NCATS) request for information on strengthening the Clinical and Translational Science Awards (CTSA) program. The AAMC is a not-for-profit association representing all 152 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic and scientific societies. Through these institutions and organizations, the AAMC represents nearly 173,000 faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The AAMC shares NCATS' commitment to improving the efficiency and effectiveness of clinical research and translational science and strengthening the CTSA program. We have discussed this request for information with many of our member institutions that are part of the CTSA consortium, and are pleased to offer comments in the following areas:

Barriers and solutions to improve use of basic research findings to inform clinical care

A successful clinical and translational science program is dependent on the ability to invest in and build the necessary programmatic and technical infrastructure. We would like to stress the importance of making funding available to support critical functions at the institutional level, such as resources for technology transfer, FDA new drug applications and investigational device exemptions, and good laboratory/manufacturing practices. As clinical research becomes increasingly reliant on advanced technology and instrumentation, researchers also need access to cutting-edge "omics" cores, biobanking, and support for data sciences. Infrastructure needs for CTSA programs will continue to rapidly expand and should be prioritized as NCATS develops future funding opportunities. Several institutions have mentioned challenges due to limited infrastructure support

currently offered through the CTSA program and suggested partially addressing this gap by linking the program with broader NIH initiatives and grants which fund infrastructure.

In broader considerations for translating basic science into clinical care, NCATS should continue to fund the "science of translational science" to identify best practices for institutions on how to develop a pipeline from basic research discoveries into clinical applications. NCATS should ensure it continues to fund early-stage, proof of concept work through the CTSA program, as this forms a necessary foundation for subsequent advances. In developing models that allow bridging of the "valley of death" in the process of product development, institutions have mentioned the Coulter Translational Research Partnership as a useful tool for researchers to better understand and adopt a milestone approach to translation. There is additionally a geographic element to how innovations can effectively move forward from an institution, depending on local connections and industry. This may also present an opportunity for NCATS to strategize on how this type of support might be more consistently available across CTSA hubs.

Workforce Development

The KL2 and TL1 clinical research training awards were cited by institutions as one of the most effective and valuable components of the CTSA hubs, in exposing pre- and postdoctoral researchers from both MD and PhD programs and a variety of disciplines to distinctive approaches to translational research as well as career opportunities both within and outside of academia. The multidisciplinary scholarship and team science promoted by these awards have been particularly effective in strengthening physician-investigator workforce training and developing institutional leaders. Several programs have also used these as an opportunity to provide trainees with mentors from different disciplines to promote a greater understanding of how basic and clinical science can be combined to address outstanding challenges in medicine.

While experiential learning in non-academic settings were identified as a valuable opportunity, institutions expressed that this is not a feasible option for all CTSA hubs, as it is limited by both funding and access to industry, and the difficulties that some trainees have in maintaining their research and/or progress to degree while being out of their primary institutional training lab for several months at a time.

Given the overall success of these training programs, institutions have identified several areas for building on the impact and effectiveness of these awards. Most CTSA hubs have a large number of applicants for these scholar and research programs and were challenged by caps on the number of awards allowed under the grant. Many institutions also expressed the need for better mechanisms to share training modules, curricula, program evaluations and outcomes between CTSA hubs. While some of these materials are published and disseminated, administrative supplements would be a helpful source of additional funding to allow more consistent inter-institutional research and collaboration on training and workforce issues.

Finally, institutions emphasized that the training programs funded by the CTSA have an impact on the learning environment that extends beyond the recipients of the awards, and that the KL2 and TL1

programs are a critical component of the CTSA program in supporting fundamental change and progress in clinical and translational science at the institutional level.

Community Engagement, Health Disparities, and Dissemination

The community engagement (CE) aspect of the CTSA program needs greater focus for institutions to effectively translate scientific advances into improved community health. Academic centers have varying levels of expertise and capabilities in this space and would be served well by increased clarity and guidance on how to best utilize institutional resources and integrate CE activities into their CTSA program.

Community health-related activities across an academic medical center are often siloed, decreasing alignment, collaboration, and impact. The AAMC encourages NCATS to increase CE-focused funding to allow the CE cores to develop into "CE hubs" tasked, in part, with weaving together community- and patient-engaged efforts across the research, clinical, and training missions of their institutions. This will facilitate collaborations, ensure community partners are not overburdened by multiple faculty requests, minimize redundancy of effort, and bring CTSA-level expertise to community- and patient-engaged projects across an academic medical center. Importantly, such a hub could act as a "front door" to community and patient partners, facilitating not only recruitment into studies, but true research, clinical, and educational partnerships from development through dissemination. CTSA driven evaluations of such hubs could catalyze development of the evidence base for what works to enhance CE/PE science and reduce inequities.

The AAMC also encourages NCATS to incentivize CE Core involvement in their hospital's and/or local community's Community Health Needs Assessment (CHNA) and Implementation Strategy process. This ACA-mandate requires not-for-profit hospitals to partner with community members and public health experts to research and prioritize local health needs, and to develop, implement, and evaluate relevant interventions. Currently, these activities are largely divorced from and not informed by CE Core leads resulting in major health equity-focused research and programmatic activities developed without scientific rigor and disconnected from other institutional efforts. Where such CE Core involvement in the CHNA process does occur (UCSF, Duke, for example) exemplary results have been achieved.

The structure of the CTSA program also affords NCATS opportunities to develop, pilot, and disseminate resources to facilitate institutions' human subjects protection processes. With the approaching January 2020 deadline for the use of single institutional review boards (IRBs) in federally funded multisite research, the CTSA program can be a model for streamlining the required reviews. The role of NCATS in developing SMART IRB to facilitate these interactions between institutions has been appreciated by the research community. The AAMC supports continued efforts by NCATS to create model forms and disseminate best practices validated through the CTSA program to assist institutions in the efficient and effective compliance with the revised Common Rule.

Additional Considerations

An overarching point of feedback from institutions was the need for greater flexibility in how institutions are able to propose and carry out research and training programs with CTSA funding. Budgetary requirements and grant criteria in the current PAR can prevent institutions from requesting or using funds for areas where they are most needed or in determining an ideal strategy or process for their own institution. Another area of concern was the need for additional project review from NCATS once a primary award has been funded, leading to delays in initiating research and other activities. Investigators stressed the need for hub leaders to be nimble in their decision-making in order to maximize the impact of the CTSA award. As part of this discussion, institutions also noted that the domains of activity that currently serve as organizing principles for CTSA hubs create an extremely broad directive and that it may be useful for NCATS to allow hubs to focus on areas which take advantage of their unique strengths and resources.

The ability to set up pilot projects within the CTSA program was also identified as a valuable mechanism, with similar requests for flexibility in the use of funds and a streamlining of the approval process. Many institutions noted the particular utility of these projects for exploring new avenues of research through proof-of-concept projects and setting up multidisciplinary collaborations—e.g. between a basic science specialist and a clinician. These smaller grants are very effective in bringing together individuals from across different units at an institution to work on issues in the health sciences.

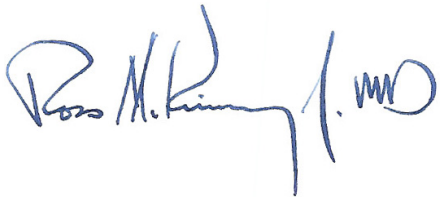
The advantages of shared activities across program hubs are evident, and institutions recommended that these collaborations be supported by NCATS, project-driven and based on shared interests between CTSA programs. The National Center for Data to Health (CD2H) is a useful example of the potential of a multi-institution CTSA network to advance biomedical tools and technologies.

The AAMC strongly supports NCATS' efforts to measure the impact of the CTSA program (as well as individual pilot projects and Centers). While academic medicine largely relies on traditional metrics of success such as grant dollars received (an input rather than an outcome) and publication in high impact journals, these metrics – while important measures for academics – are less relevant for other research stakeholders such as community members, policymakers, hospital administrators, and patients.

Through engagement with basic, clinical, and population health scientists as well as their community, administrative, healthcare, and policymaker partners, the AAMC and RAND Europe developed and published "100 Metrics to Assess and Communicate the Value of Biomedical Research." While not intended to be exhaustive, the resource provides examples of vetted "metrics that matter" to various stakeholders in the research ecosystem. A handful of the resulting metrics were piloted with the CTSA Center at the University of Wisconsin-Madison and the results were published and promising. We encourage NCATS to use the "100 Metrics" document as a resource for developing a multi-faceted, comprehensive evaluation of the Programs and Centers that can yield metrics and data points appealing to the widest array of stakeholders possible.

The AAMC appreciates NCATS' efforts to engage the relevant stakeholders in strengthening the CTSA program and would be happy to engage with our member academic medical institutions and work with the agency as it moves forward. Please feel free to contact me or my colleague Anurupa Dev, PhD, Lead Specialist for Science Policy (adev@aamc.org) with any questions about these comments.

Sincerely,



Ross E. McKinney, Jr., MD
Chief Scientific Officer