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January 8, 2016

Christopher Austin, M.D.
Director, National Center for Advancing Translational Sciences
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

RE: NOT-TR-16-002, Request for Information (RFI): Soliciting Input for the National Center for Advancing Translational Sciences (NCATS) Strategic Planning Process

Dear Dr. Austin:

The Association of American Medical Colleges (AAMC) commends NCATS for its thoughtful approach to strategic planning and for providing extensive opportunity for public input. The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. The Association's members comprise all 145 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic societies. These institutions and organizations include 148,000 faculty members, 83,000 medical students, 115,000 resident physicians, and thousands of graduate students and postdoctoral trainees in the biomedical sciences. We have encouraged our member institutions to respond directly to this RFI to convey their first-hand knowledge and perspectives on the scientific and operational challenges, opportunities and needs that they encounter with respect to translational research. The AAMC focuses its comments on several specific items requested in the RFI.

Breaking down professional, cultural and scientific silos across the translational science spectrum (RFI Item A). In addition to material support for translational research, we believe NCATS should also ensure linkages that facilitate lines of communication and collaboration. In addition NCATS should support investigation in the development, testing, and comparison of approaches among sites, projects and programs. In order to truly catalyze the translation of research, we need to create more extensive networks and increase interactions across laboratories, clinics, neighborhoods and communities as a whole. The AAMC, therefore, fully supports breaking down silos as a priority for the strategic plan, an approach reflected in the transdisciplinary and collaborative nature of biomedical research. Improved connectivity and communication help all researchers better identify problems and potential solutions. By networking projects and programs, individual research venues become like nodes in a larger system for detecting and evaluating emerging discoveries or interventions.

The AAMC recommends that NCATS advance connectivity and collaboration across disciplines and venues by being consistently clear in its expectations for such, including in its program announcements, review criteria and evaluation of programs and projects. Evaluation especially should be a component of every major program where collaborative outcomes are criteria for success. NCATS may also work to disseminate models of successful collaborations and how they were accomplished.

It is not necessary to dissolve or remove distinctions among disciplines or institutions—variation and diversity in systems are a source of strength—but to ensure that traditional or presumed boundaries are not obstacles. Effective translational research must also include participation of patients and communities, a commitment also relevant to the RFI information item E, "Forming innovative partnerships with a wide variety of stakeholders." The Clinical and Translational Science Awards consortia have exemplified such connections, while providing new structures and homes for translational investigators and cores for community engagement. Following further on the recommendations of the recent Institute of Medicine/National Academy of Medicine report, as NCATS is doing, will further strengthen the program.

Focusing on interoperability of data systems (such as integrating patient data and electronic health records into pre-clinical research) (RFI item B). The AAMC agrees that a central provision of the strategic plan should address advancing the interoperability of data systems, use of comprehensive electronic health records, genomic data and new data sources such as mobile health technology to facilitate translational science. Academic medical centers have made progress to improve interoperability and use of patient data for research; the NIH, the Department of Health and Human Services (DHHS) and other federal agencies, and the Office of the National Coordinator also play a major role. Data resources are now seen as a fundamental part of institutions' infrastructure, personnel, or administrative capacity. Among the reasons change has been so difficult is the legacy of how electronic systems and processes have evolved, often from ad hoc data sources and collections, after extensive local investment, and from the rate of technological change outpacing the availability of skilled workers and other resources. No small part of the interoperability predicament has been the fragmentation of efforts to develop data resources. *The AAMC recommends that the strategic plan specify NCATS's role in data interoperability in coordination with other important federal initiatives.* NCATS should also consider its strategic role in connection with the Precision Medicine Initiative, which the AAMC has welcomed as an historic opportunity to advance health care.

NIH should continue to foster new data standards so that datasets will be well organized, protected, accessible and reusable to enable research and allow for future interoperability. Data standards should reflect learning from other communities and take into consideration the increased value of data when developed with an eye toward future use and re-use, and potential integration with other data types drawn from other areas within biomedical and health research. Finally, we note the importance of cybersecurity and human protection. As the biomedical research community strives to better incorporate health records, genomic information, and other data, we face increasing concerns for privacy, confidentiality, and full protection for patients and

research participants. Overly rigid or inflexible security requirements can inhibit research and innovation without commensurately improving patient protection. *The strategic plan should express NCATS and NIH's dedication to addressing privacy and security of data, and ensuring balanced and appropriate protection while facilitating research.*

Focusing on patient-driven research and patient/community engagement [RFI item D]. The AAMC applauds NCATS for recognizing the essential role for patient and community engagement as a priority of the strategic plan. We have emphasized in other comments that patient engagement must not be viewed as a concession to patients or only as a means for recruitment into trials, but that engagement is a genuine partnership in research, which benefits the conduct and quality of the scientific process. With all communities, and especially underserved populations, building and sustaining trust is the first step. As the AAMC recently noted in other comments:

> Increasing the participation and sense of belonging to a broadly defined health and research-ready community will require providing incentives, expectations and resources for engaging and learning from communities to build ties and trust. This is a marathon, not a sprint, and boom-bust engagement with communities linked to funding will undermine developing effective partnerships for minority groups to benefit from discoveries. [AAMC remarks to FDA, April 1, 2014.]

The AAMC recommends that the strategic plan note that community engagement in translational research begins with recognizing the value of patients and other individuals' experiences in living with various conditions, and the environment that influences health and shapes health outcomes; and that engaging communities and patients in research is a long-term commitment, and not defined strictly by the life or term of a project.

Identifying skillsets and competencies needed for training the next generation of translational scientists [RFI item F]. The skillsets that are needed for the future translational research workforce will evolve along with the science itself, although will likely continue to include biostatistical and quantitative skills, and increased emphasis managerial, leadership and communication skills and the ability to work in teams. The AAMC has a broad perspective on the role of training and the composition of the future research workforce in translational research and biomedical science generally. As the AAMC commented to the Biomedical Research Workforce Working Group of the Director's Advisory Committee, the concept of "work force" at modern academic institutions extends far beyond faculty, research administrators, and trainees, and now embraces many types of professionals, including technicians, safety officers, managers, programmers, engineers, and others. Many of these are personnel with specific research training who are fully employed by programs at these institutions, as well as those whose services are spread across multiple missions. At its best, biomedical and health science training, both through training programs and research project grants, not only create environments for trainees to develop in-depth discipline-based expertise, but also help prepare them for a broad diversity of careers, including industry, public policy, and other areas, all of which potentially contribute to

health and medicine. Increasingly, young scientists train to work in teams and in collaborations on cross-disciplinary research. NIH and other federal agencies should recognize that education and training for such diverse and productive careers are a legitimate, valuable outcome of agency training and career development programs.

The AAMC recommends that NCATS and NIH promote training programs with team-based focus, and encourage interdisciplinary training and collaborations. NIH should also define success of training programs broadly, and revise evaluation of training programs accordingly to recognize institutions and principal investigators for training graduate students, postdoctoral fellows and physician scientists who enter broad scientific careers such as policymaking, government, community-engagement research around social determinants of health, and other topics. We have also recognized the need to disentangle "workforce" from "training" and employ multiple approaches to address research demands. The NCI for example has recently issued a program announcement for support of laboratory "staff scientist" positions to provide a professional career track for such individuals, which the AAMC welcomes.

In closing, we recognize that there is necessarily crossover among topics and priorities identified in the RFI; for example, the development of appropriate skillsets for translational research is also relevant to community engagement. We hope that the points made under any one topic will be construed as relevant to others, as appropriate.

The AAMC is again grateful for this opportunity to comment, and would be happy to provide any further information which would be of use to the NIH as it prepares a strategic plan for the future of NCATS. Please contact me or my colleague Stephen Heinig (sheinig@aamc.org) with questions about these comments.

Sincerely,

Alex Ommaya, DSc
Acting Chief Scientific Officer