



# Statement

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on

## **The Draft Translational Medicine and Therapeutic Working Group Recommendations**

Presented to the

Scientific Management Review Board  
National Institutes of Health

By

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The Association of American Medical Colleges (AAMC) is grateful to the National Institutes of Health (NIH) and its Scientific Management Review Board (SMRB) for this opportunity to comment on the draft recommendations of the Translational Medicine and Therapeutic (TMAT) Working Group. The AAMC represents all 133 accredited U.S. medical schools, nearly 400 teaching hospitals and health systems, and 90 academic societies representing 128,000 faculty members. AAMC member institutions perform more than half of all extramural research supported by the NIH. Most all of the 55 active research institutions in the Clinical and Translational Science Awards (CTSA) consortia include AAMC member medical schools and teaching hospitals.

The AAMC would first like to thank the SMRB and its working groups for their dedication and diligence in conducting a thorough review of the NIH organizational structure with consummate sensitivity to the agency's public health mission and the quality of its science. The Association actively supported passage of the NIH Reform Act of 2006 that created the SMRB and other reforms to improve management for scientific and public health priorities. Even prior to that legislation, the AAMC had long endorsed reforms to permit NIH leadership more flexibility in managing and coordinating the agency's programs to meet emerging health needs and to address scientific opportunities.

The TMAT working group presented an excellent analysis of the NIH programs for support of clinical and translational medicine, and particularly the challenges of incorporating a new entity, the Cures Acceleration Network, within an effective structure for appropriate management and oversight. These challenges are made more acute—and the SMRB mission more critical—by the severe fiscal constraints currently confronting NIH, the research community, and the Nation. NIH and the medical research community share the imperative to ensure that NIH's organization most effectively focuses limited resources on critical scientific and health priorities.

The AAMC wishes to address two issues that we request the SMRB consider in its deliberations on the TMAT recommendations, in particular the establishment of a new organizational entity. The first regards the focus and objectives of the Clinical and Translational Science Awards program, which the working group recommends be moved to the new organization. The AAMC believes that this new entity should explicitly commit to advancing the CTSA's key objectives and emerging accomplishments. One of these objectives is the promotion of community outreach and community-based participatory research, not only to develop venues for clinical trials, but also to enlist communities as partners in identifying pathways and barriers for the translation of validated science into medical practice and public health. The CTSA provide an historic opportunity for institutions and researchers to engage in long-term partnerships with communities and other organizations in health research. These partnerships involve time and resources, above all to build trust. To date, these partnerships have generated genuine enthusiasm among scientists and engaged communities, and the AAMC believes such collaborations will be among the consortia's early successes if they are allowed to develop.

Similarly, while the CTSA are still relatively new, with just the first round of the initial five-year awards coming due for renewal this year, the consortia are succeeding in their objective to establish "homes" for clinical and translational research and for the training and career development of new clinical investigators, especially physician-scientists and scientists from

other health professions. The CTSA program was conceived on such an ambitious scale specifically to integrate clinical and translational research and research training across a broad spectrum of clinical and health science, and to support the translation of new knowledge into health practice. The CTSA institutions and their community partners have invested significant resources into this program (in addition to NIH funds) because these goals have been so compelling. While drug development should be one of the objectives of the new translational entity, it should not be the only focus. The new entity must foster the ability of the CTSA's and indeed the entire medical research enterprise to engage across the full continuum of translational research, including in areas especially relevant to the implementation of health care delivery reform. The AAMC urges that NIH's commitment to the CTSA's broad objectives be incorporated as a central theme underlying implementation of the new entity, and encourages the SMRB to affirm its commitment to the total spectrum of translational research as it considers the TMAT recommendations.

The AAMC's second concern is that the TMAT working group's proposals would profoundly affect other programs within the National Center for Research Resources (NCRR), and by extension the nation's medical schools and teaching hospitals. While other Institutes and Centers do support the development of infrastructure within their missions, NCRR is the only NIH organization dedicated to development of infrastructure and resources across all fields of medical and health research. The NCRR leadership and staff, and its council representing the communities that use, develop, and manage these resources, are dedicated to serving the broadest interests of the medical and health community (a mission somewhat comparable to the NIGMS mission for fundamental research). Further, the NCRR staff have developed the necessary expertise in assessing and supporting the resource needs of the extramural research community that must be preserved in any potential reorganization. For example, the Comparative Medicine Program, which provides for animal research resources, is indispensable to medical research and is no less fundamental than other NIH programs to translating laboratory discoveries into clinical or other applications.

The NCRR has led the way in establishing shared infrastructure and networks for collaboration that serve both the best interests of science and provide for more efficient use of limited resources. The AAMC believes that attention must be given to the impact of the TMAT recommendations on these valued resources, many of which are critically important to translational medicine and the overall NIH mission. The AAMC recommends that any deliberations on moving forward with the working group's recommendations also evaluate the best way to transfer NCRR's resource programs in a way that ensures their continued focus, integrity, and effectiveness.

On behalf of the AAMC's President, Darrell Kirch, its Board of Directors and member institutions, the Association is grateful to the SMRB and the NIH for this opportunity to comment, and I would be glad to answer questions about this statement or provide further information.