January 7, 2016

Dr. Christopher P. Austin, M.D.
Director, National Center for Advancing Translational Sciences
National Institutes of Health
Attention: NOT-TR-16-002
Submitted electronically at: https://grants.nih.gov/grants/rfi/rfi.cfm?ID=50

Re: Request for Information (RFI): Soliciting Input for the National Center for Advancing Translational Sciences (NCATS) Strategic Planning Process

Dear Director Austin:

The American Medical Informatics Association (AMIA) appreciates the opportunity to submit comments regarding the National Center for Advancing Translational Sciences (NCATS) Strategic Planning Process. This request for information (RFI) was published in the October 8, 2015, issue of the Federal Register.

AMIA is the professional home for more than 5,000 informatics professionals, many of whom are NIH-funded investigators, representing researchers, front-line clinicians and public health experts who bring meaning to data, manage information and generate new knowledge across the health and healthcare enterprise. AMIA is committed to supporting the clinical and translational sciences and has for the last eleven years provided a community of practice for translational informaticians and researchers by providing forums to discuss practical and applied translational informatics issues. As part of our ongoing commitment to the translational sciences, and in particular the CTSA Program, AMIA will host a full track dedicated to professionals implementing informatics tools to support and transform translational science at the 2016 Joint Summits on Translational Science.[1] Our members contribute substantively to the CTSA Consortium and are part of NCATS success story.

AMIA believes NCATS is uniquely positioned to serve the broader National Institutes of Health, and support the goals of other Institutes and Centers, by aligning programs and developing services that reinforce the NCATS hallmarks of:

- Supporting disease-, organ system- and technology- agnostic research;
- Enhancing multidisciplinary collaboration;
- Enabling cross-institutional research and cooperation; and
- Funding programs that leverage informatics to advance translational science.

[1] https://www.amia.org/jointsummits2016

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The advent and growth of personalized medicine, especially as framed through the Obama administration's Precision Medicine Initiative, has initiated a far-reaching conversation over how best to utilize decades of research and development, reorient dozens of programs across the federal government, and capitalize on a host of emerging technologies. One outcome from this catalyzing initiative may be the realization that our siloed view of disease and organ systems is inconsistent with biology and therapy. As a result, the organizational structure at NIH – which mirrors this view – will likely need focused support systems to strengthen connections across existing and newly-developed programs. We believe NCATS is well positioned to be one of these support systems, but it must:

1. Develop ways to measure and convey how NCATS programs impact patients and institutions;
2. Define its identity as the source for "systems science" within the NIH and reorganize funding opportunities to support this identity; and
3. Ensure that informatics continues to play a vital role in the organization's success by requiring informaticians serve on all NCATS study sections.

Below we outline our recommendations in more detail. We hope our comments are helpful as you undertake this important work. AMIA would gladly welcome representation from NCATS at the 2016 Joint Summits on Translational Science, March 21 - 24, 2016, as part of the ongoing dialogue we hope to foster by responding to this RFI. Should you have questions about these comments or require additional information, please contact Jeffery Smith, Vice President of Public Policy at jsmith@amia.org or (301) 657-1291.

Sincerely,

Douglas B. Fridsma, MD, PhD, FACP, FACMI
President and CEO
AMIA

Thomas H. Payne, MD, FACP
AMIA Board Chair
Medical Director, IT Services, UW Medicine
University of Washington

Attached: Detailed Recommendations to Inform NCATS Strategic Planning Process

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First, AMIA recommends NCATS concentrate substantial effort on improving patient outcomes and the public's health. Correspondingly, measures should be developed to assess progress towards these ultimate goals. The NCATS Advisory Council Working Group on the IOM Report emphasized the need for measurable objectives.[2] AMIA members involved with the CTSA collaborative note the difficulty of generating return on investment (ROI) for NCATS-funded programs, as well as generating true outcome measures to gauge the impact of NCATS' work on patients. However, we encourage NCATS to think critically about how to build a robust feedback loop between itself and grantees, as well as provide a platform for grantees to learn from one another. This recommendation should not be construed to warrant more output data from grantees, but rather NCATS should determine ways to measure the impact of solutions it develops, projects it funds, and cures it delivers on the patients and institutions supported by NCATS programs.

AMIA recommends NCATS position itself as the source for "systems science" at NIH, leveraging the success of the CTSA Program. Systems science supports fundamental research leading to a theoretical foundation for design and systems engineering that can be integrated and abstracted to develop explanatory models in a general, domain-independent fashion. Every corner of NIH can and should benefit from the expertise cultivated and funded by NCATS. As the resource center for translational science, NCATS should reinforce its identity as the source for moving cures from "bench to bedside" by generating knowledge on the engineering of research and the science of implementing research findings to improve interventions, such as the CTSA ACT technology platform i2b2[3]. AMIA supports the recommendations of the 2013 IOM report[4] outlining opportunities to advance clinical and translational research through the CTSA Program, and we support the subsequent NCATS Advisory Council Working Group report on how to improve the CTSA Program at NIH. We applaud efforts made by NCATS to explicitly implement those recommendations and encourage further efforts to identify programs and funding opportunities that align with those reports' recommendations as a means to develop translational tools and methodologies that can be used by other parts of NIH.

We encourage NCATS to be active participants and supporters of communities of excellence, such as AMIA's translational science community, as it furthers its reputation as the national source for systems science.

Third, NCATS should orient its programs, funding opportunities and project deliverables to provide translational services that can benefit NIH Institutes & Centers. Two recent requests

[2] National Center for Advancing Translational Science. NCATS Advisory Council Working Group on the IOM Report: The CTSA Program at NIH. May 2014 https://ncats.nih.gov/files/CTSA-IOM-WG-report-5-2014.pdf
[3] Informatics for Integrating Biology & the Bedside (i2b2). https://www.i2b2.org/
[4] IOM (Institute of Medicine). 2013. *The CTSA Program at NIH: Opportunities for advancing clinical and translational research*. Washington, DC: The National Academies Press.

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for applications (RFAs) exemplify this kind of approach. RFA-TR-15-004[5] and RFA-TR-15-002[6] are meant to produce solutions to systemic problems in recruiting participants for multisite clinical trials through recruitment innovation centers (RICs) and develop innovative ways to streamline trial implementation, promote high-quality multisite trials and disseminate best practices through trial innovation centers (TICs). We urge NCATS to make a concerted effort to promote and support this kind of service-oriented research that can be applied to systems-level challenges. Further, we encourage NCATS to develop a portfolio approach, in coordination with other Institutes and Centers, to determine funding priorities.

Finally, NCATS should prioritize research that utilizes informatics tools as an enabler to improve translational science. The value of the CTSA Program, and the collaborative initiated to support it, are the shared resources created by individual participants and the availability of informatics tools to avoid duplicative effort. We suggest NCATS use funding mechanisms that (1) require explicit descriptions of how informatics and shared computing resources will be used as a component of the RFA and (2) require that any informatics tools developed in support of the project be made available to the wider CTSA Consortium, and to other NIH Institutes and Centers. To help ensure robust informatics components are appropriately included in RFAs, we strongly recommend informaticians serve on all NCATS study sections.

We note that informatics is complementary to, but distinct from, the related disciplines of information technology (IT) and statistics. IT focuses on the hardware and protocols needed to store, retrieve, and transmit data. Statistics is mathematically oriented and focuses on numerical inference. Both overlap in part with informatics in that they are concerned with collection, analysis, and interpretation of data. However, informatics is distinct from statistics in its focus on knowledge management and the engineering of information systems. Informatics draws upon computer science, decision science, information science, management science, cognitive science, and organizational theory to develop novel methods in areas as diverse as data mining, natural language or text processing, cognitive science, human interface design, decision support, databases, and algorithms for analyzing large amounts of data. By requiring informaticians to be part of NCATS study sections, taxpayers and federal financers can be assured that all NCATS projects will employ robust informatics practices and sound informatics principles, thus ensuring stronger program and project deliverables and more usable resources.

[5] Clinical and Translational Science Award (CTSA) Network Recruitment Innovation Centers (RICs) (U24) http://grants.nih.gov/grants/guide/rfa-files/RFA-TR-15-004.html
[6] Clinical and Translational Science Award (CTSA) Network Trial Innovation Centers (TICs) (U24) http://grants.nih.gov/grants/guide/rfa-files/RFA-TR-15-002.html

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