Welcome and Introductions

AAMC Chief Scientific Officer Ann Bonham, PhD, welcomed the APR and introduced everyone in the room, including the two newest members:

- Maureen Smith, MD, PhD, MPH, Director of the Institute for Clinical and Translational Research, University of Wisconsin
- Neil Weissman, MD, President of Medstar Health Research Institute and Professor of Medicine, Georgetown University

Darrell Kirch, MD, AAMC President and CEO, addressed the Panel and spoke about the uniqueness of academic medicine as a place where three high-level public goods—professional education, clinical care, and research—all coexist. Dr. Kirch also noted that the recently released Investment in Research report, a project created at the direction of the APR, sheds much-needed light on an important topic and is frequently discussed during his visits to member institutions.

Building a Shared Knowledge Base for Clinical Investigation: The Next Phase in Clinical Trials Data Sharing

- Sharon Terry, President and CEO, Genetic Alliance
- Lana Skirboll, PhD, Vice President, Academic and Scientific Affairs, Sanofi-Adventis
- Deborah Zarin, MD, Director, ClinicalTrials.gov

The discussion was framed by the three invited speakers, who represented very different perspectives, but all agreed on the need for increased sharing of clinical trial data from academic medicine. Common themes in the opening remarks centered on a need to come together as a community of patients and researchers, and to increase investigators’ level of engagement on the value of sharing data. There is also need for investment for infrastructure; qualified/dedicated personnel; and support from leadership, particularly given the increased level of compliance that will be required under proposed federal policies from HHS and NIH.

**Primary observations and action items from the discussion with the APR are as follows:**

1. **Tools and learning opportunities to highlight the value of data sharing for investigators**
   
   The AAMC can provide a venue (eg. workshop, webinar) to bring forward the value of data sharing, and share best practices to query existing data. This would facilitate understanding for scientists of how they might benefit from data sharing, and provide specific tools they can use to this end. This session could cover “tips and tricks” such as the concierge service and advanced search page on CT.gov, or algorithms to search the
data for a specific type of drug and look at how many studies have been done, in which phase, and from which company.

AAMC could also consider creating an online portal for AMCs to learn about resources around clinical trial data sharing. Beyond just a collection of links, it can also include issue briefs and, in the future, best practices for data sharing or a review of other relevant developments. The site should be able to address the question: “What are recent policy and regulatory changes which will require significant and focused effort from academic medical centers around clinical trial data sharing, and what are the available resources and groups working on this issue?”

2. **Creation of a training model for academia**

   Institutions may assign administrative personnel to complete the CT.gov registration process, but results reporting likely requires a scientist or someone with technical knowledge of the trial. A potential model for making sure these results are uploaded in a correct and timely manner is to assign a trainee/junior clinical researcher on a trial team to be the person responsible for entering the data on CT.gov. That would be an excellent training situation because it involves data analysis and understanding the protocol, while meeting a workforce issue.

**Strategies for Optimizing the Impact and Sustainability of Biomedical Research**

*Sally Rockey, PhD, NIH Deputy Director for Extramural Research*

Dr. Rockey led a discussion on creating a new paradigm and future for the biomedical research enterprise. She expressed appreciation for the partnership between the NIH and AAMC, and noted that the association is the “go-to” for data which are not available anywhere else.

The conversation was framed by the fact that the NIH doubling led to a sudden influx of money into the system which was not maintained, leading to a lack of predictability for investigators on research funding levels. If the NIH was instead funded to keep up with inflationary growth, this may have led to a more stable funding outlook and easier adjustment to growth for the research community.

Dr. Rockey reviewed some of the data and current issues around trainees, such as, the ratio of postdocs to available tenure-track faculty positions, difficulty with keeping MDs in the research system due to lack of continuous support, and the average amount of time to transition to an independent research career. Proposed ideas at NIH for the scientific workforce include creating pilots for a new staff scientist career path, and a mechanism for senior scientists to transition out of the NIH funding pool. The APR discussed whether there was consensus on the “right” size of the workforce—among the points raised were that training scientists elevates society as a whole, and that we cannot claim that we are funding too many PhDs as they are not underemployed. The size of the research enterprise continues to be a topic of discussion for the entire community.
The presentation also covered efforts to diversify the portfolio of investigators currently receiving NIH funding, including the new MIRA (Maximizing Investigators’ Research Award) grant from NIGMS. This would move away from a model of research which has to adhere to specific aims and allow PIs to follow the natural flow of research, even when it does not fall within an original research proposal.

The APR raised concerns on the issue of indirect costs, particularly, that limits on these reimbursements create a situation where smaller, and less resource-intensive institutions have trouble making up the difference in funds needed for research activities. The Panel also discussed the funding needed for building infrastructure, and trade-offs between making direct institutional grants for infrastructure vs. having a set-aside in other grants. This concept was brought up in conjunction with the idea of core consolidation, both within the institution and the development of regional cores, such as within the CTSAs. The NIH will be collecting more information on cores during the grant application process to better catalog existing facilities and determine where there might be overlap.

AAMC Advocacy Update

Dave Moore, AAMC Senior Director for Government Relations

This presentation reviewed the current state of legislation in Congress to address levels of NIH funding, and the multiple efforts in the House and Senate focused on biomedical research:

- Congressional “Dear Colleague” letters in support of the NIH were signed by 169 members of the House and 54 members of the Senate.
- The Senate recently established a NIH Caucus, chaired by Lindsey Graham (R-NC) and Dick Durbin (D-IL).
- Post-sequestration, NIH funding levels in FY13 dropped to $29.1 billion - a 5.6% decrease.
- Proposals to supplement NIH appropriations include the Accelerating Biomedical Research Act, American Cures Act, Medical Innovation Act, and Permanent Investment in Health Research Act.
- The 21st Century Cures Act (H.R. 6) contains major provisions relevant to NIH including: a three-year reauthorization at +1.5 billion/year and creating an NIH Innovation Fund that would provide $8.75 billion in mandatory funding over the next five years.
- The Senate HELP Committee also released a white paper on related issues on January 29 and has held four hearings since on medical innovation, R&D, and precision medicine.