Agency Update: NIH Advisory Committee to the Director Meets to Discuss ARPA-H, COVID-19 Response, and Safe and Inclusive Environments in Biomedical Research

Lewis-Burke Associates LLC – June 17, 2021

The National Institutes of Health (NIH) Advisory Committee to the Director (ACD) held a virtual meeting on June 10-11, 2021 to discuss programs and initiatives across NIH and hear updates from its various working groups. The most anticipated session at the meeting was a presentation from Dr. Eric Lander, Director of the White House Office of Science and Technology Policy (OSTP), on the proposed Advanced Projects Research Agency for Health (ARPA-H). In addition to discussions around ARPA-H, the ACD meeting provided updates on current progress of COVID-19 programs, NIH’s diversity, equity, and inclusion efforts through the UNITE Initiative, and the agency’s efforts to redress harassment in biomedical research. The ACD Working Group on Enhancing Rigor, Transparency, and Translatability in Animal Research presented their final report and recommendations, and staff from the new NIH Common Fund program Bridge to Artificial Intelligence (Bridge2AI) provided a summary of that program’s two open funding opportunities. The sections below summarize the conversations and expected impacts on the research community on these topics, among others.

Advanced Research Projects Agency for Health (ARPA-H)

ARPA-H, a new entity proposed by President Biden as part of his fiscal year (FY) 2022 budget request for NIH, would use disruptive innovation to “drive transformational health research and speed medical breakthroughs.” Dr. Collins opened his Director’s Report presentation by highlighting how many of the research successes seen over the past year in the fight against COVID-19 could be applied to other diseases such as cancer, Alzheimer’s disease, and diabetes. He made it very clear that he sees the newly proposed ARPA-H as an initiative that could drive these medical breakthroughs at an accelerated speed. In his presentation, Dr. Lander described ARPA-H as a solution to address the critical gap between fundamental investigator-initiated research and the commercialization that is needed to deliver more cures and treatments to patients. In the Administration’s view, ARPA-H would have a culture distinct from the NIH and would encourage bold ideas, nimbleness, and the ability to fail fast in order to enable a risk-taking culture. Of note, Dr. Lander indicated that equity should be considered in all aspects of the ARPA-H mission including some projects that are solely focused on addressing health equity. While many important details about ARPA-H’s scale, scope, and structure remain unclear, OSTP plans to organize stakeholder discussions to build support for the ARPA-H proposal and begin to address these outstanding questions.

NIH COVID-19 Response

As the nation begins to emerge from the pandemic, much of the ACD meeting was spent discussing the success and future directions of the agency’s COVID-19 research efforts. Due in large part to decades of fundamental research supported by NIH which led to the development of safe and effective vaccines, more than 50% of the nation is now fully vaccinated, and NIH leadership reiterated their commitment to addressing vaccine hesitancy as vaccination rates begin to slow. NIH remains focused on COVID-19 research through the many trans-NIH initiatives developed over the past year, and this meeting provided updates on COVID-19 related activities that have occurred since the December ACD meeting.
NIH leadership provided updates on the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) program, a public-private partnership to develop therapeutic treatments and vaccines for COVID-19, and the Rapid Acceleration of Diagnostics (RADx) initiative, which aims to expand and enhance testing for COVID-19. As the country begins to reopen, RADx is now focused on expanding diagnostics for testing populations that have yet to be vaccinated, such as children that fall below the vaccine eligibility age. In addition, NIH leadership provided updates on the Community Engagement Alliance (CEAL) Against COVID-19 Disparities program, which is working to address the disparate impact of COVID-19 in communities of color, and the Post-Acute Sequelae of SARS-CoV2 Infection (PASC) Initiative, which has been renamed to Researching COVID to Enhance Recovery (RECOVER).

Promoting an Inclusive and Safe Environment in Biomedical Research
NIH leadership also provided updates on the agency’s efforts to promote a safe and inclusive biomedical research environment. Dr. Michael Lauer, NIH Deputy Director for Extramural Research, provided an update on the progress towards implementing the ACD Working Group Recommendations on Changing the Culture to End Sexual Harassment. Dr. Lauer highlighted new NIH guidelines to “enhance diversity and create safe environments at conferences supported by NIH grants” (NOT-OD-21-053) and a notice of special interest calling for the addition of “harassment as an area of interest to research to understand and inform interventions that promote research careers of individuals in the biomedical sciences” (NOT-OD-21-068). As the NIH works to implement these recommendations, the agency continues to monitor harassment cases reported from the extramural community; this year, there are plans to establish a hotline that can be used in addition to the existing web form and email address for the community to use to report harassment incidents to NIH.

Dr. Marie Bernard, NIH Chief Officer for Scientific Workforce Diversity, provided an update on the UNITE Initiative, the agency’s new suite of programs aimed at enhancing diversity, equity, and inclusion. The presentation featured progress reports from UNITE’s five working committees. NIH anticipates releasing several reports over the coming months, including a full analysis of the request for information issued for comments and suggestions to advance the UNITE Initiative, an analysis of intramural and extramural listening sessions, and a survey of diversity, equity, and inclusion activities at each NIH Institute and Center.

Enhancing Rigor, Transparency, and Translatability in Animal Research
The working group on Rigor, Transparency, and Translatability in Animal Research provided its final report at the ACD meeting. The main charge of this working group was to identify gaps and opportunities to improve rigor, reproducibility, translation, and transparency in animal model studies. The report provided recommendations that fell under five different themes:

• Improve study design and analytic rigor;
• Address bias, incomplete reporting, and questionable research practices;
• Improve relevance and use of animal model;
• Improve methodologic and results reporting; and
• Measure and evaluate effectiveness and costs.

The full list of recommendations and sub recommendations can be found in the final report. NIH leadership will now move towards prioritizing and implementing the recommendations presented by the working group.
**Bridge to Artificial Intelligence Program**

Lastly, Dr. Gene Civillico, program lead within the NIH Common Fund Office, provided an update on the Bridge2AI program. This program aims to promote the widespread adoption of artificial intelligence (AI) and machine learning (ML) in biomedical research. The overall goal of the program is to “generate flagship datasets and best practices for the collection and preparation of AI/ML-ready data to address biomedical and behavioral research grand challenges.” Dr. Civillico discussed the two solicitations that are currently available for this program ([OTA-21-008](https://acd.od.nih.gov/meetings.html) and [RFA-RM-21-023](https://acd.od.nih.gov/meetings.html)), as well as the program’s future directions. He emphasized that a major goal of the initiative was the release and utility of data generated through Bridge2AI, and that a Plan for Enhancing Diverse Perspectives was a crucial component for all proposals. Virtual team building activities for Bridge2AI are ongoing throughout the summer.

The next meeting of the NIH ACD is currently scheduled for December 9-10, 2021.

*Sources and Additional Information:*

- The webcast of the ACD meeting and all the reports and associated slide presentations from the Working Groups are available at [https://acd.od.nih.gov/meetings.html](https://acd.od.nih.gov/meetings.html).