

**White House Office of Science and Technology Policy & National Institutes of Health**  
**ARPA-H Listening Session: Industry**  
**Friday, July 27, 2021**  
*Summary*

## Overview

On July 27, 2021 the White House Office of Science and Technology Policy (OSTP) and the National Institutes of Health (NIH) convened a listening session to provide input into the scientific focus of the Advanced Projects Research Agency for Health (ARPA-H). As part of the 90-minute listening session, representatives from 16 companies and industry associations<sup>1</sup> discussed scientific opportunities, approaches, challenges, and partnership strategies ARPA-H might adopt.

The meeting was introduced by Dr. Eric Lander, the Director of OSTP. Dr. Lander welcomed participants and explained the meeting goal, which was to engage participants in a discussion about potential research and development priorities and programs for ARPA-H. Dr. Lander noted that many innovative biomedical research ideas do not necessarily fit existing Federal government mechanisms for support nor companies' need for a return on investment over short time frames. He noted that these innovative ideas may not fit other existing mechanisms because they are high-risk, costly, require coordination across multiple parties, or do not match academia's incentives. In addition, projects that focus on remedying inequities or disparities in healthcare access are not always seen as ripe for commercial investment. He noted that flexible high risk, high reward efforts, such as those launched by DARPA, have historically been successful in supporting breakthrough technologies and that having similar capabilities and approaches applied to health offers opportunities for new breakthroughs.

After Dr. Lander's introduction, participants engaged in a question and answer session, followed by two breakout and feedback sessions moderated by Dr. Lawrence Tabak, Principal Deputy Director of NIH. The first session considered challenges and barriers facing the biomedical research ecosystem on which ARPA-H could focus. The second session considered approaches that should be considered or opportunities that could be leveraged to overcome critical challenges in the market, regulatory environment, biomedical research enterprise, or elsewhere in the ecosystem, as well as the approaches and partnership strategies an ARPA-H might employ to overcome them.

## Themes

- ***Patient data enclaves allowing large-scale analyses represent an overarching platform technology for ARPA-H.*** Participants focused on large scale computational environments and data sets as an opportunity that ARPA-H could pursue. In the United States, real-world patient data held in electronic medical records are decentralized and use a variety of data formats, making it exceptionally difficult to mine patient data for clinical and research insights. A large patient data enclave could speed novel drug development and indication expansion. Such an effort would leverage and build on the successes of the NIH-sponsored National COVID Cohort Collaborative (N3C) and the interagency COVID-19 High Performance Computing Consortium that have been used to compile and mine COVID-19 patient data. Development of such a data enclave could facilitate

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<sup>1</sup> AdvaMed Dx, Alliance for Artificial Intelligence in Healthcare, Alliance for Regenerative Medicine, Amazon, Association of Clinical Research Organizations, BIO, IBM, IQVIA, Labcorp, Medical Device Manufacturers Association, Palantir, Pfizer/Hever, PPD, Rare Disease Coalition, TransCelerate, Verily

efforts by the FDA, CMS, and other agencies to develop standards for incorporating real-world patient data as a complement to clinical trial data in regulatory and reimbursement approvals.

- ***ARPA-H could use such an enclave as the basis for the development of additional platform technologies that would be broadly useful for the biomedical research ecosystem.*** Participants identified a range of current challenges and platform technologies whose development could be facilitated by a large-scale data enclave and computing facility. One example was the identification of pre-symptomatic Alzheimer's patients for clinical testing of new interventions. Another suggestion was the development of synthetic control arms that could increase the speed of clinical trials. Also suggested was the development of new molecularly-driven diagnostic and treatment planning capabilities, which would benefit from advances in correlating molecular (e.g., genetic) and clinical phenotyping at scale. It was also suggested that the enclave could be used as the basis to develop biologically based computational systems. Participants also noted that, for technology development efforts such as these, ARPA-H performer teams will need to incorporate a substantial number of data scientists and computer scientists in addition to biosciences expertise.
- ***A range of additional opportunities were also suggested.*** One suggestion was that ARPA-H could invest in the development of large-scale quantum computing explicitly designed for healthcare and life sciences. Another opportunity identified was to focus on precise intervention delivery (e.g., for gene therapy), such as resolving challenges related to characterizing personalized therapies generated from an individual's own cells to allow for meaningful cell-based therapy approaches. Also suggested was development of technologies superior to CRISPR that allow for reproducibly reprogramming cellular functions.
- ***ARPA-H will need to pursue novel partnerships with other Federal agencies to achieve its goals.*** Given the challenges ARPA-H is intended to address, it will need to pursue innovative partnership strategies to speed innovations to patients. Close relationships with agencies, such as FDA to aid regulatory approval and with CMS to facilitate coverage/reimbursement, were recommended by participants. Further, the VA, with its large patient network and integrated electronic medical records system, was suggested as another potential partner for ARPA-H efforts. It was suggested that ARPA-H could serve as a convener and neutral forum for participants across the innovation ecosystem, including regulators and industry.
- ***ARPA-H should use its authorities and process flexibilities to facilitate industry partnerships.*** Participants highlighted the value of the authorities and process flexibilities that would be needed to add agility to ARPA-H, including rapid contracting capabilities and quick decision-making by program managers and leadership. They also suggested that ARPA-H should focus on developing an approach to intellectual property (IP), similar to DARPA, that would facilitate industry participation – both with respect to IP developed as a result of ARPA-H programs and to managing the IP performers bring to the research. Finally, participants suggested that ARPA-H could facilitate the formation of research consortia involving many stakeholders, including industry, which might serve to transition innovations to market.

## **Next Steps and Conclusion**

OSTP and NIH will continue to seek perspectives on ARPA-H from stakeholders within and outside the Federal government. This was the third of a series of listening sessions convened to solicit feedback from particular communities. Additional sessions with scientific societies and other stakeholders will occur in August. OSTP and NIH will use interagency processes to ensure that ARPA-H complements the priorities of NIH and is coordinated with the efforts of other Federal research agencies. OSTP and NIH are grateful for

the participation and perspectives provided by the wide variety of stakeholders in these listening sessions. Much work remains to ensure that the biomedical ecosystem is engaged in solving some of the most pressing health challenges of our time. The Administration will continue to work to ensure that the US remains a global leader in biomedical innovation for the benefit of all Americans.