



**WHITE HOUSE OFFICE OF SCIENCE AND
TECHNOLOGY POLICY
&
NATIONAL INSTITUTES OF HEALTH LISTENING
SESSIONS FOR ARPA-H: SUMMARY REPORT**

September 2021

About the Office of Science and Technology Policy

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About this Document

From July 14 to August 16, 2021, the Office of Science and Technology Policy (OSTP) and the National Institutes of Health (NIH) held a series of fifteen listening sessions with stakeholders across the biomedical ecosystem to seek input on the Advanced Research Projects Agency for Health (ARPA-H). Of the fifteen listening sessions, ten sessions, led by NIH, focused on specific research areas and involved the NIH Institute and Center (IC) Directors and Deputy Directors, as well as invited organizations, who presented prepared statements. These sessions were open to the public and provided an opportunity for real-time question submission and response. The remaining five sessions, led by OSTP, were invite-only and were attended by various stakeholder organizations, representing patient advocacy groups, biomedical professional groups, venture capital firms, private industry, and other non-biomedical STEM professional organizations. The Science and Technology Policy Institute (STPI) was charged with facilitating these discussions and summarizing the findings. Attached is a summary document of the major themes that arose across the fifteen listening sessions ranging from specific project or program proposals, potential collaboration avenues, and operational considerations.

This summary was prepared by STPI at the request of the Office of Science and Technology Policy, Executive Office of the President and does not necessarily reflect the views or position of STPI.

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Table of Contents

ARPA-H Listening Session: Background.....	1
Scientific Emphasis.....	1
Embrace Equity and Diversity as a Cornerstone of ARPA-H’s Mission	3
Process	4
Collaboration.....	6
Next Steps	6
Appendix A: NIH Listening Session Participant List.....	8
Appendix B: OSTP Listening Session Participant List	11

ARPA-H Listening Session: Background

This document summarizes the findings of a series of listening sessions on the Advanced Research Projects Agency-Health (ARPA-H) conducted during July and August 2021—a set of 15 listening sessions convened by the White House Office of Science and Technology Policy (OSTP) and the National Institutes of Health (NIH).

Ten of the sessions, hosted by NIH, were focused on particular research areas, such as cancer, genomics, eye disease, biomedical imaging, translational research, and mental health. These public, open sessions consisted of remarks from OSTP and NIH leadership, including relevant NIH Institute and Center (IC) Directors and Deputy Directors, and statements from up to 10 organizations per session. These remarks were followed by an open question and answer period in which the audience could participate directly.

The remaining five meetings, hosted by OSTP, were smaller, invitation-only sessions that began with a short overview of ARPA-H and question and answer session conducted by either Dr. Eric Lander of OSTP or Dr. Francis Collins of NIH. This introduction was followed by interactive breakout sessions to further identify the opportunities and challenges that ARPA-H may consider addressing. Following each of the breakout sessions, the participants presented their findings as a group with short discussions based on their suggestions. These five sessions included stakeholders from patient advocacy groups, industry, philanthropy organizations, venture capital firms, biomedical professional groups, and other STEM professional groups in fields including economics, mathematics, physics, and engineering.

More than 5,000 individuals registered for these sessions, providing nearly 1,000 suggestions, ideas, and questions across the 15 sessions. While individual meeting summaries have been made public,¹ this document synthesizes participant suggestions and recommendations regarding the future of ARPA-H from across the full set of 15 sessions.

Scientific Emphasis

Center around technologies, rather than specific diseases. An emphasis on cross-cutting technologies with wide applications across diseases would maximize ARPA-H's effect on patient outcomes. Similar to the transformative nature of polymerase chain reaction (PCR) platforms that revolutionized molecular biology and are used across multiple disciplines, ARPA-H programs should promote and advance specific technological capabilities that can be applied to solve disease-specific questions. Several more specific themes are outlined below:

Data sharing platforms and universal data standards and systems were suggested as transformative areas that are ripe with opportunity and would not only be cross-cutting,

¹ [Individual](#) session summaries can be found at: [Events | National Institutes of Health \(NIH\)](#)

but could also collapse the barriers resulting in data siloes. Importantly, this would allow for more integrative research approaches. By developing and implementing consistent data standards, research efforts can be more efficient, transparent, and equitable. Also, integrating electronic health record (EHR) systems to foster the creation of unified patient medical profiles holds enormous potential to optimize patient-focused care. Integrated data systems could also more robustly connect genetic and molecular biomarker information with phenotypic data to understand their relationships and develop a more holistic view. Another suggestion was to convene interdisciplinary teams to harness naturally occurring data—such as cell phone movements, consumer expenditures, health care records, and population-level data—to characterize linkages between health care delivery and social systems.

Rapid and accessible early detection, diagnosis, and treatment platforms have the potential to revolutionize preventative medicine and treat patients at or before the onset of disease. Similar to current treatments for HIV/AIDS, ARPA-H could develop sensitive tests and drugs for diseases with no or limited treatment options, like Alzheimer’s, that could be administered at initial diagnosis, even before symptoms appear. Other suggestions focused on the period before disease onset: encouraged by the advances in diagnostics that were propelled by the response to the COVID-19 pandemic, there is a tremendous opportunity for diagnostic platforms that can analyze individualized data like biomarkers or environmental and societal influences in order to detect disease *before* it occurs. Other, more specific suggestions included using optical coherence tomography to detect neurodegenerative diseases by scanning the eye, creating a “Google Map” of individual patients to model a person’s health profile, or making a “Facebook for treatments” that can offer individualized treatment suggestions using integrated health data coupled with artificial intelligence (AI).

Artificial intelligence and machine-learning algorithms can be developed to optimize integration and analysis of diverse patient datasets to identify connections otherwise not easily observed or readily identifiable by human analysis alone. It was suggested that ARPA-H could develop or leverage large-scale quantum computers to combine AI and quantum mechanics to analyze large collections of EHRs to tie predictive markers to health outcomes. Participants suggested building upon the success of the National COVID Cohort Collaborative (N3C) and the COVID-19 High Performance Computing Consortium to compile and mine COVID-19 patient data for clinical and research insights. Dramatically improving and expanding use of AI algorithms to analyze medical imaging data was a specific area identified by participants that could benefit from ARPA-H support. Special consideration should be given to ensuring that these algorithms and models minimize bias so that every American benefits from the results.

Wearables and digital technologies could be developed to collect information longitudinally—throughout development, the lifespan, or the disease course—to help

inform both fundamental knowledge and preventative, diagnostic, and therapeutic approaches. Wearables could provide a wealth of untapped data and could be used to record baseline biomarkers, disease symptomology, and health outcomes, coupled with data that provides insight on the environment, activity levels, and more, to inform future interventions. For example, it was suggested that smart watches could be applied during clinical trials to improve data collection, or they could be used in geroscience to optimize the independence of elderly populations by identifying digital phenotypes of disability and illness. Other suggestions included using mobile phone applications and global positioning systems to alert those with alcohol use disorder when near settings that put them at a higher risk of relapse and leveraging advances in digital technology to improve upon current hearing aids, making them smaller, cheaper, and more affordable. The accessibility of wearables and other technologies could also contribute to improving inclusion of hard to reach populations, especially those in rural areas.

Prioritizing programs that consider individuals holistically, including behavior and the context for these behaviors, including the microbiome, physical, chemical, and social environmental exposures, cultural and behavioral factors, communities and social support systems, and economic factors that influence health. Particularly for ARPA-H and its emphasis on use-driven research, it is important for biomedical researchers to consider a whole health approach instead of focusing on disease-directed outcomes.

Developing new treatment technologies, such as nanoparticulate drugs, gene therapies, long-term formulations, and other precise delivery mechanisms, could be used to treat diseases from liver fibrosis to rare diseases.

Embrace Equity and Diversity as a Cornerstone of ARPA-H's Mission

Participants suggested that diversity and inclusion should be considered in everything ARPA-H undertakes: during the recruitment of its team members, including program managers and business and administrative leads, during the development and selection of programs, and during the execution of projects. Moreover, efforts should be made to ensure that all Americans have access to innovations supported by ARPA-H especially among underrepresented and vulnerable populations. Without unique and varied perspectives incorporated at all levels and in all processes, there is risk of homogeneity in thinking, underestimating specific challenges or overlooking novel approaches, and excluding those who may benefit from the output. In particular, ARPA-H should strive to recruit diverse leadership and program managers, who can lay the foundation for inclusive scientific programs and actively break down barriers to collaboration.

NIH has many existing programs that could be leveraged for effective engagement with underrepresented groups; those suggested include the Hispanic Community Health Study, the *All of Us* Research Program, the Research Centers in Minority Institutions (RCMI), and the Native American Research Centers for Health (NARCH). ARPA-H

should engage early with communities, including Tribal Nations and communities, that will implement or benefit from its innovations to understand and incorporate their priorities and feedback. Stakeholders suggested that ARPA-H should prioritize supporting programs that specifically target health equity, including developing imaging diagnostic tools that more accurately differentiate between skin colors and/or do not bias skin tones or other physical features (e.g., facial recognition technology), identifying predictive biomarkers for at-risk individuals, developing new models for genetic testing and counseling that could reach diverse and underserved populations, and creating low-cost diagnostics for increased accessibility in rural or hard to reach areas.

ARPA-H should also embed equity in the proposal review and award stages. Diversity of performer teams, including the recruitment of researchers from diverse institutions, was proposed as a review criterion. Participants also highlighted the use of community advisory boards to provide diverse input from those considered the ultimate “customers” or “users” during the program development and/or review stage. It was also suggested that a committee of external experts could review ARPA-H and its portfolio to ensure programs are fulfilling equity needs. During clinical trials, ARPA-H should work with patient advocacy groups and community organizations to recruit diverse participants—thereby ensuring that population-specific factors are incorporated in the final results. These organizations already have established, trusted relationships with their communities that ARPA-H should leverage.

Process

Complement NIH’s research portfolio. Stakeholders advised ARPA-H to avoid areas that are already well-resourced by NIH or the private sector. Instead they suggested that ARPA-H should focus on ambitious, large-scale research topics that are complementary to and do not overlap with efforts at the various NIH ICs, especially those research problems that are not compatible with traditional academic or commercial research funding structures. Developing novel genetic testing platforms, which are currently too expensive and time-consuming for widespread use, may also be a topic suitable for exploration by ARPA-H. There were also suggestions regarding the need for a culture distinct from that of the rest of NIH, as well as broad autonomy and independence. To do so, ARPA-H’s leadership should embrace the opportunity to establish an entirely different approach—from utilizing a more managed process for the programs it supports to simply employing new naming conventions for the different methods and mechanisms it uses. Participants also proposed that ARPA-H should strive to be transformative, generating unique perspectives and approaches that build a “high risk, high reward” mindset into the culture.

Establish mechanisms for commercialization and bringing products to market early in the process. Building on the goal of supporting use-driven research, participants

discussed the need to design ARPA-H for ensuring that program deliverables are able to navigate regulatory and reimbursement hurdles; establishing strong relationships with the U.S. Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid (CMS) was cited as a key mechanism for doing so. In partnering with academia, as well as industry, participants underscored that ARPA-H will require effective and rapid procedures for human subjects review, contracting and acquisitions, and licensing and patenting discoveries. Partnerships with pharmaceutical companies, hospital systems, the insurance industry, and others will also be essential to address key logistical challenges that impede implementation progress and slow delivery to patients, such as establishing stable supply chains during manufacturing, working with CMS to ensure insurance reimbursement, and having robust distribution systems for ARPA-H-developed treatments and technologies. While ARPA-H should not base investments solely on their potential for commercial success, addressing these and other challenges will accelerate transitioning successful discoveries into clinical use.

Adopt streamlined processes to expedite discovery. Mimicking a process similar to DARPA, participants suggested that ARPA-H use a two-step process to expedite review. This would involve submission of an initial, short (e.g., one-page) concept that could be reviewed quickly, followed by a full-length proposal that would be submitted, should the initial concept be accepted, and reviewed. Contracts and other transaction mechanisms should provide the flexibility to enforce milestones, adapt projects as needed, or terminate projects that are not progressing. Although the ARPA model was viewed favorably, participants acknowledged that ARPA-H should further streamline the administrative oversight and reporting expectations that currently exist in the model.

Capitalize on recruiting diverse, interdisciplinary performer teams while training the next generation of scientists. Repeated throughout the sessions were the essential aspects of flexibility, particularly that of program managers, and diversity, including for staff, performers, scientific disciplines, and partners. Participants suggested that ARPA-H program managers should have the authority to convene teams regardless of their educational backgrounds or career stages. In addition to biomedical researchers, ARPA-H teams should draw upon disciplines, such as social and behavioral scientists, physical scientists, biostatisticians, librarians, data scientists, mathematicians, engineers, economists, sociologists, criminologists, anthropologists, and public health experts, who would bring unique expertise and perspectives to ARPA-H programs and could provide insight into and address the roots of health inequities. Community leaders and “boots on the ground” healthcare providers also should be involved from the early stages of projects, as they will be the ones that ultimately interact with, influence and inform, and treat patients.

Participants suggested that ARPA-H should support fellowship programs, early-career faculty awards, and/or mentorship programs for undergraduate and graduate

students that would attract a diverse and passionate candidate pool. ARPA-H program managers could benefit from tapping into the networks of existing programs, such as the Building Infrastructure Leading to Diversity (BUILD) program² and the Institutional Development Award (IDeA) Networks of Biomedical Research Excellence (INBRE) program,³ as well as advocacy organizations, to recruit these talented individuals.

Collaboration

Incorporate diverse, multi-disciplinary collaboration approaches. Stakeholders highlighted the need for creating broad partnerships that involve Federal Government agencies, academic institutions, biopharmaceutical and other industries, patients, and other non-governmental entities. Beyond FDA and CMS, additional Federal agencies mentioned as potential research partners included the Centers for Disease Control and Prevention (CDC), the U.S. Department of Veterans Affairs, and the Environmental Protection Agency (EPA). One specific suggestion was to develop a streamlined process to identify new, targeted therapies for existing drugs and move them into market faster by including non-traditional partners, guidance from regulatory agencies, and Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR) programs. Stakeholders also suggested that including community advisory boards at the early planning stages of ARPA-H programs could provide more locally relevant and culturally sensitive guidance. The Patient-Centered Outcomes Research Institute (PCORI) approach to including community organizations in research planning was suggested as a potential model. Stakeholders suggested many other community organizations with which to collaborate, including Community Engagement Alliance against COVID-19 Disparities, Centers for Population Health and Health Disparities, as well as the Centers of Excellence on Minority Health and Health Disparities, and the preclinical Accelerating Medicines Partnership (AMP).

Next Steps

While these listening sessions have concluded, OSTP and NIH will continue to seek perspectives from stakeholders on ARPA-H. Public comments can be submitted to ARPAHcomments@nih.gov. The Administration has also convened a Fast Track Action Committee (FTAC) of the National Science and Technology Council (NSTC) to identify synergies between ARPA-H and the work of NIH and other Federal agencies and to promote interagency coordination, where appropriate, in the design of ARPA-H's approach. OSTP and NIH are grateful for the participation and perspectives provided by the stakeholders in these listening sessions. Much work remains to ensure that the biomedical ecosystem and the Nation's research communities strengthen their existing connections to solve some of the most pressing health challenges of our time. The

² [Building Infrastructure Leading to Diversity \(BUILD\) Initiative \(nih.gov\)](#)

³ [IDeA Networks of Biomedical Research Excellence \(nih.gov\)](#)

Administration will continue to work to ensure that the United States remains a global leader in biomedical and health innovation for the benefit of all Americans.

Appendix A: NIH Listening Session Participant List

NIH: NCI, NEI, NHLBI, NHGRI, NIA, NIAAA, NIAID, NIAMS, NIBIB, NICHD, NIDCD, NIDCR, NIDDK, NIDA, NIEHS, NIGMS, NIMH, NIMHD, NINDS, NINR, NLM, FIC, NCATS, NCCIH

Academy for Radiology & Biomedical Imaging Research

AcademyHealth

ACT for NIH

Ad Hoc Group for Medical Research

Addiction Policy Forum

Allen Institute for Brain Science

Alzheimer's Association

American Academy of Ophthalmology

American Academy of Optometry

American Academy of Otolaryngology-Head and Neck Surgeons

American Academy of Pediatrics

American Association for Dental, Oral, and Craniofacial Research

American Association for the Study of Liver Diseases

American Association of Colleges of Nursing

American Association of Physicists in Medicine

American Cancer Society

American Cleft Palate-Craniofacial Association

American College of Medical Genetic and Genomics

American College of Neuropsychopharmacology

American Congress of Rehabilitation Medicine

American Gastroenterological Association

American Geriatrics Society

American Heart Association

American Institute of Medical and Biological Engineering

American Medical Informatics Association

American Neurological Association
American Psychiatric Association
American Public Health Association
American Society for Bone and Mineral Research
American Society of Hematology
American Society of Human Genetics
American Society of Nephrology
American Speech-Language-Hearing Association
American Thoracic Society
Association for Clinical and Translational Sciences
Association of American Cancer Institutes
Center for Strategic and International Studies
Coalition for Clinical and Translational Science
College on Problems of Drug Dependence
Consortium of Universities for Global Health
Council for the Advancement of Nursing Science
Endocrine Society
Food Allergy Research and Education
Foundation Fighting Blindness
Friends of NIAAA
Friends of NIMH
Future of Research
Gerontological Society of America
Global Health Technologies Coalition
Hearing Loss Association of America
Interdisciplinary Association for Population Health
International Society for Computational Biology
Lymphatic Education and Research Network
Medical Library Association

National Alliance for Hispanic Health
National Brain Tumor Society
National Bureau of Economics Research
National Minority Quality Forum
National Society of Genetic Counselors
Population Association of America
PRIDEnet
Public Health Institute
Research Society on Alcoholism
Research!America
Rheumatology Research Foundation
Sickle Cell Disease Association of America, Inc.
Sjögren's Foundation
Society for Investigative Dermatology
Society for Prevention Research
Society for Women's Health Research
Society of Biological Psychiatry
Society of General Internal Medicine
The Assistance Fund
The Institute for Integrative Health
Treatment Action Group
Whole Health Institute

Appendix B: OSTP Listening Session Participant List

Academy of Arts and Science
AdvaMedDx
Alliance for Artificial Intelligence in Healthcare
Alliance for Regenerative Medicine
Alzheimer's Association
Amazon.com, Inc.
American Academy of Nursing
American Academy of Pediatrics
American Anthropological Association
American Association for Cancer Research
American Association for the Advancement of Science
American Association of Colleges of Nursing
American Autoimmune Related Diseases Association
American Cancer Society
American College of Radiation Oncology
American Dental Association
American Diabetes Association
American Heart Association
American Hospital Association
American Institute of Biological Sciences
American Institute of Physics
American Liver Foundation
American Mathematical Society
American Medical Student Association
American Physical Society
American Public Health Association
American Society for Cell Biology
American Society for Microbiology

American Society for Tropical Medicine and Hygiene
American Society of Gene & Cell Therapy
American Society of Mechanical Engineers
American Statistical Association
Association for Computing Machinery
Association for Information Science & Technology
Association for Psychological Science
Association for Women in Mathematics
Association of American Medical Colleges
Association of Clinical Research Organizations
Association of Independent Research Institutes
Association of Public and Land-grant Universities
Bay City Capital
BIO
Biophysical Society
Chan Zuckerberg Initiative
Chronic Pain Research Alliance
Coalition for the Life Sciences
Cohen Veterans Bioscience
Consortium of Social Science Associations
Council of Medical Specialty Societies
Critical Path Institute
Deadliest Cancers Coalition
EveryLife Foundation for Rare Diseases
FasterCures
Federal Laboratory Consortium for Technology Transfer
Federation of American Societies for Experimental Biology
Federation of Associations in Behavioral & Brain Sciences
Flagship Pioneering

Foundation for the National Institutes of Health
Fred Hutchinson Cancer Research Center
Friends of Cancer Research
Gates Foundation
Genetic Alliance
Global Alzheimer's Platform Foundation
Howard Hughes Medical Institute
Human Biology Association
IBM
Infectious Diseases Society of America
Institute of Electrical and Electronics Engineers
IQVIA
JDRF
Kaiser Family Foundation
Kavli Foundation
Labcorp
MacArthur Foundation
Mathematical Association of America
Medical Device Manufacturers Association
Moore Foundation
National Academy of Medicine
National Bureau of Economic Research
National Health Council
National Laboratory Directors' Council
National Organization for Rare Disorders
National Postdoctoral Association
New America
Palantir
Patient-Centered Outcomes Research Institute

Peterson Center on Healthcare
Pfizer Inc.
PPD
Rare Disease Coalition
Reagan-Udall Foundation
RTI International
Salk Institute for Biological Studies
Schmidt Futures
Society for Industrial and Applied Mathematics
Society for Neuroscience
Society for the Advancement of Chicanos/Hispanics and Native Americans in Science
SPIE
Stand Up to Cancer
The American Society of Hematology
The Jackson Laboratory
The Rockefeller Foundation
TransCelerate Biopharma Inc.
UsAgainstAlzheimer's
Verily
Wellcome
XPRIZE Foundation