DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2025

Advanced Research Projects Agency for Health

Congressional Justification for Appropriations Committees

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Director, ARPA-H

I am pleased to present the Advanced Research Projects Agency for Health's (ARPA-H) FY 2025 President's Budget Request This budget justification outlines the request for $1.5 billion to further propel ARPA-H's mission to *accelerate better health outcomes for everyone*. With these funds, ARPA-H will expand the portfolio of programs, bolster mission offices, and continue to recruit program managers (PMs), while executing and taking big technical risks that will catalyze biomedical innovation.

The advanced research project agencies (ARPA) model is not driven by a top-down strategy, but rather by the ideas and solutions of PMs and their unique vision for efforts that will accelerate the path to better health outcomes for everyone. Modeled after several ARPAs, ARPA-H applies a proven organizational structure, technical rigor, and streamlined award processes to fund innovative and impactful programs through unique acquisition authorities, which allow commercial-like business relationships with non-traditional vendors in the health ecosystem.

Since its establishment in March 2022, ARPA-H has implemented industry best practices to align organizational strategic planning, management, and accountability. In December 2023, the inaugural *ARPA-H Strategic Plan for Fiscal Years 2024-2026* was published, which articulates a holistic framework of goals and objectives for business and technical mission areas, including:

1. Expand technical possibilities for the future of health.
2. Forge a resilient health system to ensure optimal well-being for all.
3. Drive scalable solutions to improve health care access and affordability.
4. Build proactive health capacity to keep people from becoming patients.
5. Foster data-driven innovation across the health ecosystem.
6. Increase the probability of successful transition.
7. Build a world-class organization.

Through implementation of this strategy, ARPA-H will address the most urgent challenges in the health ecosystem: escalating rates of chronic diseases, inequitable access to high-quality health care, vulnerabilities in data security and privacy, critical gaps in prevention and treatment strategies for cancer, limited availability of effective interventions for neurodegenerative diseases, the ongoing mental health and substance use disorder crises, the continued need for pandemic preparedness, and the rise of antimicrobial resistance, among many others.

ARPA-H will make pivotal investments to tackle longstanding health problems, while simultaneously remaining agile to respond to emerging issues. The agency will develop new tools, technologies, and approaches in collaboration with federal, state, and local government officials, health care providers, researchers, and domestic and international communities. ARPA-H embraces novel public/private partnerships to ensure productive program design and to establish viable transition pathways upfront. Through this model, ARPA-H will accelerate health outcomes by transitioning solutions to our numerous partners, constituents, and, most importantly, the American people. Together, we will unlock new frontiers in health research and innovation, where bold ideas become tangible realities.

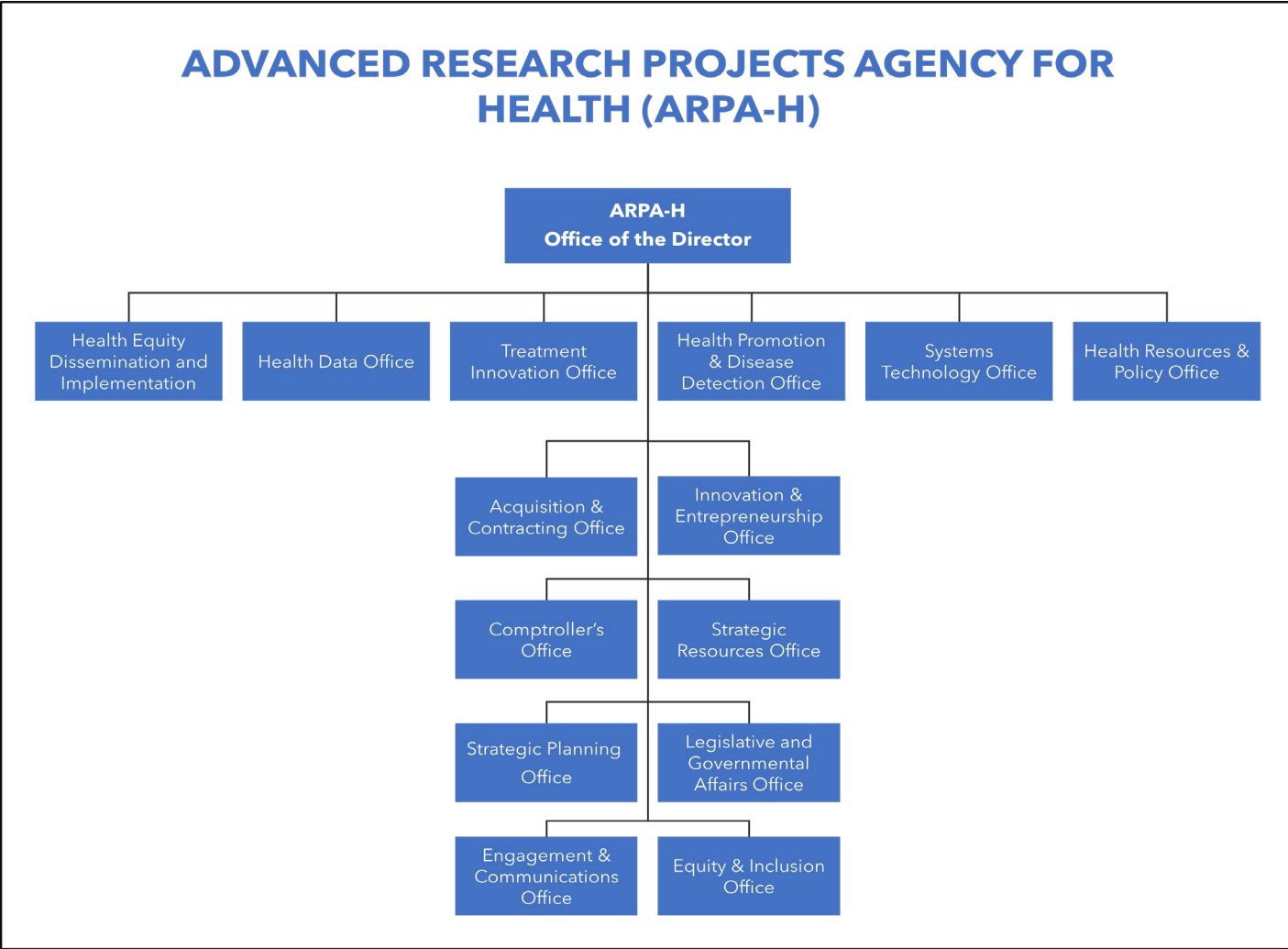Renee D. Wegrzyn, PhD

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Section I: Executive Summary

Organization Chart

ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH (ARPA-H)

- **ARPA-H Office of the Director**
  - Health Equity Dissemination and Implementation
  - Health Data Office
  - Treatment Innovation Office
  - Health Promotion & Disease Detection Office
  - Systems Technology Office
  - Health Resources & Policy Office
  - Acquisition & Contracting Office
  - Innovation & Entrepreneurship Office
  - Comptroller's Office
  - Strategic Resources Office
  - Strategic Planning Office
  - Legislative and Governmental Affairs Office
  - Engagement & Communications Office
  - Equity & Inclusion Office

Note: ARPA-H is adjusting its Organization Chart in accordance with the Consolidated Appropriations Act, FY2023.This adjustment reduces the organization offices from 14 to 8.

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Introduction and Mission

The ARPA-H mission is to accelerate better health outcomes for everyone, which is reinforced by ARPA-H's core organizational values that emphasize innovation, agility, and high-impact outcomes. ARPA-H is committed to solving the most challenging problems in health by developing research and development (R&D) programs that will accelerate medical breakthroughs and turn what seems impossible into tangible realities for better health. ARPA-H is developing entirely new ways to tackle the hardest challenges across the health ecosystem, advancing high-risk, high-impact biomedical and health R&D that cannot be readily accomplished through traditional research or commercial activity.

To effectively execute its mission, ARPA-H embraces industry best practices, including due diligence review of existing R&D activities, rigorous program design, competitive project selection, thorough performer evaluation, and active program management to ensure optimized and impactful resource expenditures. ARPA-H employs an active portfolio development approach that identifies programs based on clearly defined problems in the health ecosystem, led by the expertise from ARPA-H PMs. This distinguishes ARPA-H from other federal health R&D organizations in that *ARPA-H does not have a pre-ordained or passive portfolio requirements approach*. This uniqueness is critically important to allow ARPA-H to fund only those programs with the greatest opportunities to transform the health ecosystem rather than forcing funds alignment to programs or projects that only provide incremental results. Finally, ARPA-H's streamlined funding awards process enables the agency to act quickly and catalyze cutting-edge biomedical and health R&D. This empowers ARPA-H to rapidly address longstanding problems in the health ecosystem with leading-edge solutions and, in parallel, allows ARPA-H to be agile in responding to emergent issues without delays inherent to more protracted funding award approaches.

ARPA-H is committed to advancing the Nation's R&D priorities. This budget request includes advanced R&D designed to accelerate better health outcomes for *every* person. It describes R&D to improve the early detection and treatment of cancer and to accelerate cancer research. Furthermore, it highlights new approaches to address antimicrobial resistance and identify emerging pathogens before they become pandemics. ARPA-H will also explore novel innovations to improve public health, equitable access to high-quality care, and diverse representation across clinical trials, including new investments to advance women's health. Throughout this budget request, ARPA-H describes programs to advance the trustworthiness of artificial intelligence (AI) technology and biotechnology, mitigate biosafety and biosecurity risks, and bolster R&D innovation. Further, ARPA-H will be a catalyst for R&D investments that advance manufacturing and drive the R&D innovation that will build the Nation's future economic competitiveness in the healthcare space from the bottom up and the middle out. This budget also highlights areas where ARPA-H is working in lock step with national security partners to accelerate the transition of biosecurity and advanced cyber security capabilities across the health ecosystem, by adding essential R&D advances that will foster equitable adoption across underserved health organizations. ARPA-H is committed to diversity in all its forms and is poised through its mission to accelerate better health outcomes for everyone.

Overview of Budget Request

For FY 2025, the President's Budget request for ARPA-H will support program investments that address specific, urgent, and challenging problems in health and the business operations that drive the agency forward. The ARPA-H FY 2025 President's Budget request is $1.5 billion, the same level as FY 2023. This request aligns to the Department of Health and Human Services' (HHS) and the Administration's priorities and ensures that ARPA-H continues to mature and accelerate programs designed to revolutionize the detection, diagnosis, mitigation, prevention, treatment, and cure of diseases and health conditions for all Americans.

Focus Areas

Like other ARPAs, ARPA-H creates new capabilities and solves problems through ambitious, well-defined, and measurable programs and projects. ARPA-H will make strategic investments to develop high-impact capabilities or platforms to drive biomedical breakthroughs—ranging from molecular to societal—that will provide transformative solutions for all individuals. The focus areas below illustrate the types of work and impact that ARPA-H will pursue through program investments.

- *Health Science Futures: Accelerating Foundational Advances in Medical Research.* Expand what is technically possible by developing approaches that bring radically new insights and paradigms. This focus area targets innovative tools, technologies, and platforms that can apply to a broad range of diseases that affect large populations, rare diseases, or diseases with limited treatment options.

- *Scalable Solutions: Improving Health Care Access and Affordability.* Reach everyone quickly by addressing challenges that include geography, distribution, manufacturing, data and information, and economies of scale to create programs that improve healthcare access and affordability.

- *Proactive Health: Developing Breakthrough Capabilities to Mitigate the Risk of Disease Onset and Progression.* Keep people from becoming patients by creating new capabilities to identify and characterize disease risk, reduce comorbidities, and promote treatments and behaviors to improve health and wellness, reducing the likelihood of medical intervention or accelerating recovery and regeneration capabilities.

- *Resilient Systems: Driving Advances in Health Systems.* Create capabilities, develop mechanisms, and accelerate system integrations to enhance health ecosystem stability and reliability to persevere through crises. Advances will span from the molecular to the societal scale, explore human-centric designs, and foster health system resilience to pandemics, natural disasters, injuries, cyber-attacks, and financial challenges.

Cancer Moonshot

Through its own R&D investments, due diligence to identify unique "white space" to address, and through robust engagement with Federal partners and stakeholders, ARPA-H is helping lead and advance the goals of the Cancer Moonshot initiative. This includes efforts with a goal towards ending cancer as we know it, along with the development of solutions for prevention, early detection, novel therapies, care delivery and support. ARPA-H will invest in the development of

transformational technologies that will improve the health of all people, including people at risk for developing or currently living with cancer and cancer survivors. ARPA-H will leverage cross-government infrastructure (e.g., data, networks) and program implementation pathways to translate ongoing research efforts into capabilities for researchers or patients, to invest in the development of breakthrough technologies, and to solve problems prioritized in the Moonshot.

Increasing Accessibility and Expanding Scale

In FY 2025, ARPA-H will continue to push the frontiers in increasing accessibility, affordability, and expanding the scale of novel health innovations to improve health outcomes for everybody. ARPA-H will invest in unmet needs for women's health and long-standing challenges in behavioral and mental health. ARPA-H will also work to stem the increasing gap in access to high quality health care in rural America. Moreover, ARPA-H will directly invest in driving affordability in the emerging areas of gene therapies that have the potential to improve the health and lives of many individuals but is still prohibitively expensive and out of reach for so many Americans. Finally, ARPA-H will support scaling key enabling capabilities necessary to enable domestic biomanufacturing, which will both accelerate development of novel drugs and therapeutics, but also democratize access to the bioeconomy not just in historic centers of bioinnovation, but across the United States.

Artificial Intelligence, and Health Ecosystem Cybersecurity

ARPA-H, established to take on some of the highest risk/highest reward challenges across the health ecosystem, is uniquely poised to address the emerging areas of AI, rapidly closing the gap from hype to implementable reality, and to drive leading edge health system cyber security in an era of increasing risk. ARPA-H will also continue to lead efforts within the health sector to identify technical gaps on health ecosystem cyber vulnerabilities, including at the individual, institution, and systems level both within the government and in the public and private sectors.

Further, development and use of foundational generative AI - such as large language models (LLMs) to scale and accelerate health and life sciences research - presents several challenges that will not be overcome with current public or private sector investments. ARPA-H will directly invest in the development of biochemical foundation models for applications ranging from prediction modeling for chemical absorption, distribution, metabolism, excretion, and toxicity (ADMET) to drug discovery; address barriers to data privacy and security; increase the quality and quantity of data available for unique model training needs; advance interpretability to support regulatory decision-making; and develop technologies that enable trustworthy, safe, and ethical development, maintenance, and use of AI technologies in the health ecosystem. ARPA-H's unique authorities and approach to program design and funding will allow the agency to move quickly and develop breakthroughs on a vastly accelerated timeframe while ensuring all necessary safeguards are in place.

Conclusion

The FY 2025 ARPA-H President's Budget request for $1.5 billion, aligns with the HHS and Administration's priorities, aiming to revolutionize health care for all Americans. The budget will support investments in ambitious, well-defined programs and projects that address urgent health problems and improve business operations. Key focus areas include Health Science Futures,

Scalable Solutions, Proactive Health, and Resilient Systems, all aimed at driving biomedical breakthroughs and improving health care access, affordability, and resilience. The budget also supports the Cancer Moonshot initiative, aiming to end cancer as we know it. ARPA-H will also invest in the development and use of AI to accelerate health and life sciences research, addressing challenges such as data privacy and security, and improving interpretability for regulatory decision-making. Lastly, the budget includes provisions for strengthening IT and cybersecurity infrastructure, including the development of a Zero Trust Architecture to safeguard critical systems. The FY 2025 ARPA-H request reflects a bold commitment to transforming healthcare through innovation, collaboration, and enhanced infrastructure, ensuring a healthier future for all Americans.

Overview of Performance

ARPA-H is committed to building and maintaining an agency culture of continuous improvement and accountability. The agency prioritizes development of metrics-driven systems and processes to inform organizational, operational, and programmatic decision-making across all levels. There are five components of ARPA-H's approach to organizational performance management.

First, in accordance with the Consolidated Appropriations Act, 2023, ARPA-H submitted its inaugural Strategic Plan to Congress on December 28, 2023. This plan outlines ARPA-H's overarching goals, actions, and key outcomes that will guide the agency in achieving its mission over the next three years.

Second, through aligned planning processes, ARPA-H divisions and offices integrate industry best practices to identify Objectives and Key Results (OKRs) performance indicators to facilitate evidence-based tracking and transparent internal reporting to strive for excellence in performance and drive accountability at all levels. The ARPA-H inaugural set of OKRs focused on five elements: building the agency, creating our network, advancing our programs, driving accessibility to health innovation, and advancing strategic management to build trust and accountability. ARPA-H current OKRs focus on maturing the agency's capabilities. As in industry, the objectives and underlying key results remain dynamic as the agency evolves to maintain impact and scales towards steady state operations.

Third, ARPA-H continues to use the rigorous scoping and evaluation approach called ARPA-(H)eilmeier Questions, to evaluate ideas and determine suitability for the high-risk, transformative health problems suitable for the agency's model. The approach is based on a set of questions developed by former Defense Advanced Research Projects Agency (DARPA) Director, George H. Heilmeier (1975-1977). ARPA-H adapted the original Heilmeier Questions to incorporate the agency-specific tenets of broad population relevance, accessibility, and real-world applications—tenets central to its mission. Potential ARPA-H PMs must answer the ARPA-(H)eilmeier Questions during the hiring process to ensure PMs with the most ambitious but rigorously vetted ideas are selected by leadership, and that these PMs begin at ARPA-H with a directional focus that increases the likelihood of program success.

Fourth, PMs develop their programs with a robust set of quantifiable metrics and milestones to base funding decisions and go/no-go continuation of awards and active and responsible management of government funds. ARPA-H's guiding principles stipulate that mission activities and programs will be time-bound and milestone-driven, with clear "midterm" and "final" exams to evaluate progress and success. PMs work directly with ARPA-H leadership to identify technical milestones that align to program and budget checkpoints. Monthly, quarterly, and annual reviews will examine progress and budget execution. This active program management approach allows PMs to provide guidance and oversight to program teams, and to redirect resources, as needed, to assure best use of funds.

Finally, operational support staff are carefully guided to align their performance priorities with the programmatic strategic planning, management, and performance measurement processes. ARPA-H is committed to effective financial stewardship and risk management to foster prudent use of resources and maintain public trust. ARPA-H participated in the NIH Enterprise Risk Management program in accordance with Office of Management and Budget A-11 and A-123 and annual

reporting requirements. As part of this process, the agency continues to establish accurate, transparent, and on-time financial reports and justifications, develop documentation on standard business processes and establish integrated data management and governance policies. Agency funding documents are vetted through multiple subject matter experts to ensure quality control and funding availability. Following technical, programmatic, and other internal approvals, funding is strategically aligned to R&D efforts and carefully monitored to ensure fiscal responsibility throughout program execution. All these efforts and many others are evolving as the Agency establishes performance measure norms.

All Purpose Table
Advanced Research Projects Agency for Health

(Dollars in millions)

Activity	FY 2023 Final		FY 2024 CR		FY 2025 President's Budget		FY 2025 +/- FY 2023	
	$	FTE	$	FTE	$	FTE	$	FTE
ARPA-H								
Total, ARPA-H Program Level	**1,500.000**	**47**	**1,500.000**	**112**	**1,500.000**	**137**	**--**	**+90**
Total, ARPA-H Discretionary Budget Authority	**1,500.000**	**47**	**1,500.000**	**112**	**1,500.000**	**137**	**--**	**+90**

Section II: Appropriation Account Title

Appropriation Language

Advanced Research Projects Agency for Health

For carrying out section 301 and part J of title IV of the PHS Act with respect to advanced research

projects for health, $1,500,000,000, to remain available through September 30, 2027.

Language Analysis

Language Provision to be Changed	Justification/Explanation
...to remain available until September 30, [2026] *2027*:	The proposed revision maintains the three-year availability of appropriations in FY 2025 that Congress provided to ARPA-H in FY 2024.

Amounts Available for Obligation
Advanced Research Projects Agency for Health

(Dollars in millions)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget
General Fund Discretionary Appropriation:			
Appropriation (L/HHS)	$1,500.000	$1,500.000	$1,500.000
Total, Discretionary Appropriation	**$1,500.000**	**$1,500.000**	**$1,500.000**
Offsetting collections from:			
Federal Funds	$0.100	$0.100	$0.100
Unobligated Balances from Prior Year(s):			
Unobligated balance, start of year (75-22/24-0837)	$957.581	$132.543	$0.000
Unobligated balance, start of year (75-23/25-0837)	$0	$1,415.216	$135.000
Unobligated balance, start of year (75-24/26-0837)	$0	$0	$546.000
Unobligated balance, end of year (75-22/24-0837)	$132.543	$0	TBD
Unobligated balance, end of year (75-23/25-0837)	$1,415.216	$135.000	TBD
Unobligated balance, end of year (75-24/26-0837)	$0	$546.000	TBD
Unobligated balance, lapsing	$0	$0	$0
Total, Available for Obligation	**$2,457.681**	**$3,047.859**	**$2,181.100**
Total, Obligations*	$909.922	$2,366.859	TBD

* FY 2024 obligations are expected obligations

Summary of Changes
Advanced Research Projects Agency for Health

(Dollars in millions)

	Dollars	FTEs
FY 2023 Final		
Total estimated budget authority......................................	$1,500.000	47
FY 2025 President's Budget		
Total estimated budget authority......................................	$1,500.000	137
Net Change..	**-$0**	**+90**

	FY 2023 Final		FY 2025 President's Budget		FY 2025 +/- FY 2023	
	BA	FTE	BA	FTE	BA	FTE
Increases:						
Built-in:						
Annualization of 2023 civilian pay increase	$13.061	47	$43.990	137	+$30.929	+90
Subtotal, Built-in Increases..					*+$30.929*	*+90*
B. Program:						
Operations						
Rental Payments to Others	$0.093	--	$2.733	--	+$2.640	--
Research and Development						
Research and Development Contracts	$734.169	--	$855.577		+$121.408	
Subtotal, Program Increases..					*+$124.049*	*--*
Total Increases..					**+$154.977**	**+90**
Decreases:						
A. Built-in:						
1. Infrastructure (GSA Rent)	$0	--	$0	--	--	--
Subtotal, Built-in Decreases..					*--*	*--*
B. Program:						
Operations						
Other Services	$183.188		$28.211		-$154.977	
Subtotal, Program Decreases..					*-$154.977*	*--*
Total Decreases..					**-$154.977**	**--**
Net Change..					**-$0**	**+90**

Budget Authority by Activity
Advanced Research Projects Agency for Health

(Dollars in millions)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
ARPA-H Technical Programs & Projects				
Total, ARPA-H Program Level	$ 1,500.000	$ 1,500.000	$ 1,500.000	$ -
Total, Budget Authority	**$ 1,500.000**	**$ 1,500.000**	**$ 1,500.000**	**$ -**
FTE	47	112	137	90

Authorizing Legislation
Advanced Research Projects Agency for Health

(Dollars in millions)

	FY 2024 Amount Authorized	FY 2024 Amount Appropriated/[1]	FY 2025 Amount Authorized	FY 2025 President's Budget
<u>Activity</u>: ARPA-H Programs Part J, Title IV of the Public Health Service Act, Section 499A	$ 500.000	$ 1,500.000	$ 500.000	$ 1,500.000

1. Amount appropriated in FY 2024 is by way of Continuing Resolution (P.L. 118-35).

Appropriations History Table
Advanced Research Projects Agency for Health

	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
FY 2022				
General Fund Appropriation:				
Annual...................................	$ -	$ -	$ -	$1,000,000,000
Subtotal.......................................	$ -	$ -	$ -	$1,000,000,000
FY 2023				
General Fund Appropriation:				
Annual...................................	$5,000,000,000	$2,750,000,000	$1,000,000,000	$1,500,000,000
Subtotal.......................................	$5,000,000,000	$2,750,000,000	$1,000,000,000	$1,500,000,000
FY 2024				
General Fund Appropriation:				
Annual...................................	$2,500,000,000	$500,000,000	$1,500,000,000	$ -
Continuing Resolution (P.L. 118-22).	$ -	$ -	$ -	$1,500,000,000
Subtotal.......................................	$2,500,000,000	$ 500,000,000	$1,500,000,000	$1,500,000,000
FY 2025				
General Fund Appropriation:				
Annual...................................	$1,500,000,000	$ -	$ -	$ -
Subtotal.......................................	$1,500,000,000	$ -	$ -	$ -

Section III: Narratives by Activity

Summary of the Request

(Dollars in thousands)

ARPA-H	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Appropriation	$1,500,000	$1,500,000	$1,500,000	$ -
FTE	47	112	137	+90

In FY 2025, ARPA-H is committed to continuing to meet its mission of accelerating better health outcomes for everyone through pivotal investments in advanced R&D of breakthrough technologies. The ARPA-H FY 2025 President's Budget request is $1.5 billion, the same level as FY 2023 Enacted. At this level, ARPA-H will increase staffing by 25 FTEs for a total estimated staffing level of 137 FTEs, which includes a total of 50 program managers onboard by the end of FY 2025.

This budget request will support ARPA-H's complementary focus areas: *Scalable Solutions*, to enhance the access and affordability of technologies, *Health Science Futures*, to accelerate R&D breakthroughs in medical research sciences, *Proactive Health*, to expand efforts resulting in illness prevention and prolonging periods of health and wellbeing and, *Resilient Systems*, to improve the robustness and adaptability of systems that affect health, while also utilizing its unique *Transitioning Capabilities* aiming to revolutionize technology commercialization across all focus areas.

Together, advances across the focus areas will propel robust healthcare access and treatment distribution across all geographies and socio-economic populations. These advances will be applicable to a range of specific diseases, including enabling ARPA-H to make its unique contribution to the President's Cancer Moonshot initiative.

ARPA-H will continue to tackle the most challenging health problems, by seeking Program Managers with innovative solutions. ARPA-H has been diligently working to ensure the agency's environment cultivates the best ideas, bringing together dynamic PM-led teams that advance high-potential, high-impact biomedical and health research. As an ARPA, the agency seeks to fund these solutions through rigorous program design, a competitive project selection process, and active program management to ensure thoughtful and impactful expenditures. ARPA-H programs are generated through the selection of these highly innovative PM ideas, pursuing health solutions that cannot be readily accomplished through traditional research or commercial activity.

ARPA-H funds two general categories of R&D efforts, 1) specific *programs* and 2) single *projects*. Specific programs are large efforts that fund multiple teams, all working to achieve the goals of the program as laid out by the PM. Specific programs are initiated by the PM and ideas are solicited through a program specific Broad Agency Announcement (BAA). Single projects involve one funded team, typically received through our open BAA. While single projects are still led and directed by the PM, the initial concept idea is typically brought to ARPA-H through the open BAA rather than the direct solicitation of concepts from specific programs. For example, in addition to targeted program announcements that may use cancer as a use case, ARPA-H is acting on a strong

pipeline of transformative proposals from the public that tackle cancer-specific challenges and advance platform technologies that could apply to cancer. With the FY 2025 budget, ARPA-H will utilize these and many other efforts to address the hardest challenges that cannot readily be accomplished through traditional research or commercial activity.

Health Science Futures: Accelerating Foundational Advances in Medical Research

Program Description

The Health Science Futures focus area, currently one of the most robust focus areas for ARPA-H, will expand what is technically possible by developing approaches that will remove the scientific and technological limitations that stymie progress towards the healthcare of the future. ARPA-H supports cutting-edge, often disease-agnostic research programs that have the potential for translational real-world change. Considering the current healthcare challenges that we face today, the goal of achieving better health outcomes is a moving target that requires daring and adaptable solutions. ARPA-H awardees will develop innovative technologies, tools, and platforms that can be applied to a broad range of diseases. The following thrust areas, categorize the ground-breaking research we seek to support:

- Breakthrough Technologies: Paradigm shifting technologies that will change how we approach the diagnosis, treatment, and impact of diseases and conditions.
- Transformative Tools: Novel, agile solutions that will move from bench to bedside quickly, facilitating revolutionary advances in medical care.
- Platform Systems: Adaptable, multi-application systems and technologies that are reconfigurable for a wide variety of clinical needs.

Current Health Science Futures efforts include:

The Precision Surgical Interventions (PSI) program envisions a future when cancer surgeries do not require reoperations and do not cause unintentional harm to the patient. This program aims to develop technologies for intraoperative microscopic visualization and automatic and precise reading of tumor margins, bedside or in vivo, without a pathologist, in less than 15 minutes, allowing increased accuracy and better ability to identify and spare critical structures. Recent advances in microscopy, computer vision, robotics, and machine learning (ML) algorithms have transformed industry but have been slow to enter the operating room. PSI aims to leverage these new technologies to create surgical devices, including devices for bedside and in vivo intraoperative microscopic visualization of resected tumor margins and the resection cavity, and intraoperative detection of critical anatomical structures and the conveyance of that awareness to the surgeon. PSI aims to decrease the positive margin rate to no more than 2%, and to decrease the avoidable anatomical injury rate by 90%. Additional approaches will be investigated to improve surgical procedures, including those facilitating advances in autonomous surgery. The technology developed during PSI will thus improve patient outcomes by decreasing reoperation rates, mortality rates, healthcare costs, and surgical complications.

ARPA-H is also prioritizing scientific and technological advances to accelerate cures for specific diseases. For example, the **Novel Innovations for Tissue Regeneration in Osteoarthritis (NITRO) program,** will develop new technologies for the regeneration of cartilage and bone ravaged by the onset of osteoarthritis (OA). OA is the third leading cause of disability in the United States, affecting 32 million Americans and representing an economic burden of $136 billion annually. The NITRO program aims to address current issues surrounding OA treatment by

developing new ways of helping the human body repair its own joints. NITRO is focused on three technical areas: non-invasive bone regeneratives, non-invasive cartilage regeneratives, and replacement joints built from human cells. This program seeks to develop technologies that will ultimately be tested for safety and initial efficacy in a phase I clinical trial of patients representing diverse populations affected by OA. To streamline the translation of OA therapeutics to patients and mitigate risk and regulatory hurdles, the NITRO program aims to establish industry standards for an ideal large animal model and in vitro model of OA. To this end, NITRO has hosted the first of a bi-annual symposium series and gathered critical data from key stakeholders related to the top in vivo, in vitro, and ethical considerations for selection of OA models.

To create entirely new tools to combat infectious disease threats, ARPA-H developed **the Antigens Predicted for Broad Viral Efficacy through Computational Experimentation (APECx)** program. Over 270 viruses are known to infect humans, yet less than 10% of these threats have vaccines regularly used in the U.S. We still lack the tools to prevent and treat viral infections that are leading causes of cancer and chronic illness. The APECx program aims to create a toolkit that enables broadly efficacious vaccine and therapeutic discovery through protein structure prediction and engineering. The APECx toolkit, and subsequent product development, would demonstrate the possibility of broadly efficacious vaccines and therapeutics against viral threats and prevent disease from entire types of viruses that are responsible for causing cancer, autoimmune disease, chronic illness, emerging infections, and potential pandemics. APECx would provide patients, healthcare providers, and the overall economy with a new approach to viral disease prevention. These tools would result in a substantial decrease in disease burden, which will significantly improve global morbidity and mortality as well as mitigate the effects on healthcare-related costs and economic output related to viral outbreaks.

ARPA-H will also explore **novel use cases for new therapeutic modalities including RiboNucleic Acid (RNA), gene, and cell-based therapeutics** that work with the body's immune system. These projects, selected from proposals submitted to the Open BAA, will have a multifaceted focus: 1) targeted delivery of therapeutics, including RNA, to specific disease tissues, 2) novel use cases of new drug modalities, and 3) more efficient engineering and manufacturing of cellular and gene therapies. To achieve these goals, ARPA-H will cultivate several novel therapeutic modalities targeting many of the highest-impact disease classes and health conditions afflicting the American population, including cancer and autoimmune diseases, and common medical complications such as transplant rejection. In addition, ARPA-H will utilize these projects to develop and validate new immunomodulatory methods, models, and tools for treating cancer and autoimmune conditions. Further, funding for these efforts will enable ARPA-H to target and reverse disease pathogenesis and enhance immune plasticity, focusing on the development of revolutionary therapeutics more widely available to all. Specific methodologies to be used will include gene modulation to program immune cell function (using RNA delivered directly to immune cells), neurobacterial platforms to target tumors and regulate the tumor microenvironment, and transplantable epithelial cells.

Novel gastrointestinal (GI) delivery mechanisms for therapeutics project, another current effort originally selected against the Open BAA, will develop technology to deliver complex

therapies via pills or pill-sized devices rather than via surgery, infusion, or injection. These oral treatments will enable self-administration of complex medicine at home, and will reduce healthcare worker involvement, the need for hospitalization, and overall healthcare costs. On a population level, this will generate a therapeutic modality that could decrease the impact of social determinants, such as socioeconomic status and proximity to care, on health. Specific modalities include pill-sized therapeutic devices that can sense their location in the gastrointestinal tract (GIT) and then either painlessly inject mRNA into the GIT lining or electrically stimulate it to produce metabolic hormones.

Many of the best available therapeutic approaches for diseases ranging from cancer to central nervous system (CNS) conditions have an unacceptably high incidence of adverse effects. ARPA-H's **Novel Drug Delivery Paradigms to Access Difficult Tissues projects** aim to provide possible solutions to this issue by developing technologies for more reliable, locally delivered therapeutic agents. The overarching goal of these Open BAA projects is to develop and validate a set of scalable and disease agnostic methods that could be targeted to any tissue, transforming the treatment of cancer, CNS conditions, and complex diseases such as autoimmune conditions. Specific projects and methodologies in this area include: 1) programming immune cells (e.g., T cells), which can traverse the body freely, to transport a therapeutic payload and 2) engineering minimally invasive bioelectronic implants, that can monitor a patient's disease state and adjust their locally delivered therapeutic dose in real time. If successful, this will shepherd the creation of groundbreaking and innovative platforms to deliver therapeutics at the right place, time, and amount, to be efficacious with minimal side effects.

Additional efforts at ARPA-H will seek to develop ground-breaking, new diagnostic modalities for rapid and early detection of disease and dysfunction. Research in the **Innovative Diagnostics and Imaging** projects, currently underway, will enable diseases to be diagnosed with state-of-the-art imaging on inexpensive and/or portable devices, and for organ dysfunction to be identified with assessments that are as quick and easy as a blood pressure reading. Potential approaches include but are not limited to new and advanced imaging techniques, miniaturized, ultrasound/photoacoustic-based tumor sensing endoscopes, and novel integration of multiple imaging modalities, all with end products capable of widespread use in clinical care. Accuracy across the diagnostic process from pre-analytic to post-analytic will be enhanced, enabling improved detection of pathologic conditions, including cancer, before they are clinically apparent.

Earlier detection of cancer translates into an increased likelihood of treatment response, overall survival, and decreased health care costs. To address this challenge, ARPA-H has launched the **Cancer and Organ Degradome Atlas (CODA) project** through the open BAA**.** CODA aims to address both the current unmet need for population-level screening across a broad range of cancer types as well as the limitations hindering accurate early cancer detection and tissue localization. CODA will advance accurate, early cancer detection and tissue localization through the development of the first detailed, degradomics atlas to provide a thorough understanding of the dysregulation of cellular processes common in the formation of cancer. This atlas will inform the design and use of novel, highly selective biomarkers in vivo to detect multiple cancers at the earliest stages of cancer cell development, thus improving disease-specific survival. Collectively,

CODA, and the resulting set of biosensor tools, can enable a multi-cancer early detection platform. CODA is uniquely suited for ARPA-H as it maps to the President's Cancer Moonshot initiative through its focus on high-impact early cancer detection across a wide variety of cancer types.

ARPA-H is committed to helping lead and advance the goals of the **Cancer Moonshot** initiative. This includes efforts posed with a goal towards ending cancer as we know it, along with the development of solutions for prevention, early detection, novel therapies, care delivery, and support. In addition to the CODA detection effort described above, other research endeavors will explore synthetic biology approaches for both novel diagnostics and therapeutics and will leverage groundbreaking advances in radiotherapy and ultrasound technology. ARPA-H will invest in the development of transformational technologies that will improve the health of all people, including people at risk for developing or currently living with cancer and cancer survivors.

Over 100,000 patients are awaiting lifesaving organs; however, only 21,000 donors (living and deceased) provide organs each year. Thus, many patients die while awaiting a transplant. Beyond organs, tissue transplants are a critical need with over 3.3 million tissue grafts taking place in America in 2021. The **Direct Production of Replacement Organs** Open BAA project initiated in FY 2024 will not only resolve the roadblock of availability but also greatly reduce the cost. Advances in stem cell biology and other regenerative therapies, biomaterials, computational modeling and machine learning, and 3D bioprinting will be leveraged to manufacture complex tissues and organs, as well as to transplant donated tissues and organs more successfully, including organs once viewed as too challenging to transplant. Research in this program space will also transform post-transplant care with enhanced monitoring of patient response. An additional use case for manufactured tissues and organs is the testing of medications in patient-matched tissue. Efforts to overcome the barriers associated with developing new transplantation modalities are challenging if not impossible outside of an ARPA framework. Foundational advances will be pursued in cellular engineering, transcriptional modification, and tissue regeneration coupled with new manufacturing paradigms to make these technologies a reality for patients.

Children make up 20% of the population, but medical research rarely focuses on them as a group with specialized medical needs. Instead, children are often treated with off-label or scaled down versions of adult solutions that do not result in the best outcomes. A program planned to begin in FY 2025, the **Pediatric Innovations** program will address unmet needs in pediatric diagnosis and treatment by developing solutions that close important gaps in treatment options between children and adults. This program will develop fast and safe imaging techniques, implants that grow with a child, and devices and drugs that are optimized for children's anatomy and physiology to replace the use of off-label adult solutions.

The **Neurodegeneration and Brain Injury Solutions** program, anticipated to begin in FY 2025, will create a paradigm shift in how brain aging, injury, and disease are conceptualized, diagnosed, and treated. Research in this thrust area will develop technology to provide personalized diagnoses and treatment for complex diseases such as Alzheimer's Disease and frontotemporal dementia. Innovative diagnostics will be developed to detect hormone changes in the brain, providing very early diagnoses while pioneering new approaches in women's healthcare by allowing for the integration of sex difference in disease course into treatment. Novel applications of treatments

such as neurostimulation will be explored as well as the possibility to reverse permanent brain injury with engineered tissue that fully integrates with the adult brain, restoring function.

Under the **Bench to Bedside Accelerator** program anticipated to begin in FY 2025**,** safe and effective drugs will enter the clinical pipeline at a faster rate, a higher rate of success, and at a lower cost. One line of effort under this program will develop digital toolkits to enable translational success for new drugs. This will be achieved through accelerated ex vivo and in vitro assays, novel computational tools that have been trained on in vivo data, and in vivo studies for tool kit validation. These tools will also result in the reduction of animal model use and catalyze the development of safe small molecules and biologics, built on a backbone of novel computational tools and data that make drug development more predictable, safer, and more accessible.

Scalable Solutions: Improve Healthcare Access and Affordability

Program Description

The Scalable Solutions focus area will drive a focus to improve healthcare access and affordability by supporting applied R&D that enables medical technologies to quickly reach a greater number of patients. For many diseases, viable interventions exist, but these interventions do not reach the patients who need them most due to misalignments in cost, form factor, or supply chains. Efforts aligned with this focus area will address these limitations by prioritizing R&D towards the following technical areas: (1) streamlined drug discovery, (2) accelerated drug repurposing to reduce cost, (3) manufacturing advances to improve efficiency and economies of scale, and (4) implementing novel approaches to reduce supply chain bottlenecks and drive down distribution cost. Finally, R&D to improve healthcare access will explore new form factors for medical devices and innovative delivery mechanisms for healthcare, including next-generation devices for homecare settings, utilization of enhanced digital devices, and advances to enable widespread adoption of mobile healthcare technologies.

ARPA-H aims to create initiatives to expand accessibility of healthcare and medicine to serve larger populations. ARPA-H will explore advanced biomanufacturing solutions to lower prices, strengthen supply chains, and improve timelines to life-changing products. Expansion in this area includes investment in innovative methods to produce critical starting materials at a scale not currently available within the United States. The manufacture of critical raw materials associated with many of these advanced therapies are currently limited to a small number of overseas suppliers, resulting in severe supply chain limitations, while also serving to drive the costs of these novel, lifesaving technologies into a realm that stands to make it inaccessible for many applications.

Additionally, ARPA-H will seek to prioritize research and development efforts aimed at creating scalable health care technologies and interventions that reduce cost and can be rapidly deployed and adapted to various populations.

ARPA-H also aims to build partnerships for collaborative distribution networks to address challenges related to geography, and ensuring equitable, quick, and efficient "last mile" delivery of health care solutions.

The FY 2025 President's Budget request will allow ARPA-H to continue to develop a portfolio of investments in these focus areas.

***Proactive Health*: Developing Breakthrough Capabilities to Mitigate the Risk of Disease Onset and Progression**

Program Description

ARPA-H is seeking solutions to improve the health span and health outcomes of Americans to mitigate the risk of disease onset and progression and/or the development of diminished quality of life from illness. Despite huge advances in the development of novel medical therapies, Americans still live with poor health outcomes and suffer from the ill-effects of disease. Current medical research and the medical delivery system in the United States focus primarily on the reactive treatment of illnesses, even though many diseases or their ill-effects are preventable.

ARPA-H's Proactive Health focus area will invest in the following research areas that could drastically improve the health of Americans throughout their lives through the 1) development of novel early-detection methods and prophylactic interventions, 2) population-level improvements in access to and uptake of disease prevention and wellness-promoting behaviors, and 3) system level innovations that increase the efficiency and delivery of proactive health capabilities. To meet these goals, ARPA-H will develop programs that capitalize on innovation opportunities in each of these specific areas:

- Novel prevention, detection, and prophylactic treatment methods for disease: new approaches that can quickly scale to detect and prevent diseases and/or the onset of their ill-effects.
- Scalable and effective approaches to increase the mass adoption of prevention and wellness behaviors: novel methods to disseminate and incentivize the adoption of healthy lifestyles, early detection, and preventative treatments of diseases that can effectively reach large and disparate populations across America.
- Innovation for systems that deliver proactive health outcomes: novel approaches that build new, collaborative processes between health care providers, technologists, and community stakeholders to develop comprehensive and personalized approaches to proactive health management. Health systems innovations should include novel outcome measurement tools, reimbursement models, and experiment-driven regulatory/policy designs that promote, reward, and pay for preventative services.

Current Proactive Health efforts include:

The **ML/AI-Aided Therapeutic Repurposing In eXtended uses (MATRIX)** project, awarded in FY 2024 through the Open BAA, attempts to create an automated capability to discover new treatments for diseases using existing drugs. If successful, MATRIX could expand the applicability of FDA approved drugs that already have commercial scale production (and potentially optimized production costs) while also containing costs. This capability could result in safe, widely accessible treatments for new diseases being developed 5X faster, and with less than 1% of the cost to develop new drugs.

If successful, ARPA-H will enable effective, population-level delivery of prevention, wellness, and prophylactic treatment across disparate and underserved communities in America.

The FY 2025 President's Budget request will allow ARPA-H to continue to develop a portfolio of investments in these focus areas.

Resilient Systems: Drive Advances in Health Systems

Program Description

ARPA-H will drive innovations that enhance the adaptability, reliability, and interoperability of the health ecosystem. These innovations will foster flexibility and enable adaptation to system stressors, so that people and systems remain well-positioned to deliver high-quality care and improve health outcomes.

ARPA-H's Resilient Systems focus area will drive advances in health systems to improve their resilience, robustness, integration, and ability to adapt to unforeseen events. Aspects of today's health and public health systems remain fragile due to systemic challenges, which-include rising healthcare costs, inadequate healthcare coverage for significant populations, outdated infrastructure, and health disparities among different demographic groups. Acute challenges, such as hospital closures, supply chain disruptions, staffing shortages, cyber-attacks, public health crises, and the emergence of new diseases, exacerbate existing fragilities, making it more difficult to maintain high standards of care. These challenges are compounded by the fact that systems remain fragmented, hindering the ability to gain comprehensive insights, make informed decisions, develop tailored interventions, and share critical health information between stakeholders.

In the health ecosystem of the future, digital health capabilities will play a central role in improving patient outcomes. Electronic systems touch everyone in the healthcare ecosystem from patients to clinicians to researchers, and enhancements are needed to connect people in a way that leads to higher standards of care. To address these challenges, ARPA-H will explore novel approaches to modernize systems, provide time savings to healthcare workforces, increase quality of care across geographies, improve data interoperability, make it easier for patients and clinicians to make informed decisions, and reduce gaps between advanced research and clinical care.

Current Resilient Systems efforts include:

To enhance the effectiveness of clinical workflows, reduce the cognitive burden on clinicians, and enable next-generation software systems to better assist people across the healthcare ecosystem, ARPA-H will support **fundamental advances in safety and accuracy of AI techniques with programs and projects in FY 2024 and FY 2025**. For example, ARPA-H will advance data science capabilities for cancer to make it easier for patients, clinicians, and researchers to gain insight from clinical trials and pre-clinical research.

The **Biomedical Data Fabric (BDF) Toolbox** effort, currently underway, seeks to address technical challenges that make it difficult to combine biomedical research data by advancing high-fidelity data collection, integration of electronic health records, semantic mapping, large language model query mechanisms, and multi-source data exploration. Currently, cancer centers and labs regularly generate large volumes of research data, but the ability to integrate data across hundreds of research efforts remains elusive. Although many advancements have been made in recent years that have moved cancer to a treatable more chronic disease, cancer continues to be the second leading cause of death in the United States and too many cancers are still not curable without the

risk of remission. The BDF Toolbox will create the ability to combine biomedical research data from thousands of labs, hospitals, and centers to accelerate the country's ability to develop next-generation health interventions, first in cancer and ultimately across disease areas. BDF will explore scalable strategies to make it easier to combine clinical research data in multiple disease areas to fuel research that improves survival and quality of life outcomes for patients across the United States.

Digital Healthcare Security (DIGIHEALS) project, launched in FY 2023, will advance digital health security, software assurance, and software usability technologies to address weaknesses in current U.S. health care infrastructures to increase system resiliency and improve the quality of care rendered to patients. Cyberattacks on the healthcare system are an ever-increasing problem for patient safety. This susceptibility to hackers also endangers the ability of hospitals and medical centers to react to emergencies. ARPA-H will work to mitigate cybersecurity risks by developing novel cyber security capabilities that address unique challenges faced by health organizations. These efforts will advance new approaches to resilient architectures; building in security by design; strengthening security and resilience for critical health infrastructure, and integrating social, behavioral, and economics research to improve the adoption of cybersecurity technologies across the health sector.   The result will be a health system where technology works to improve patient care through increased safety and security as well as positively impact the experience of seeing a physician by increasing face-to-face interactions since medical providers will no longer need to battle an outdated and cyberattack-prone system.

AI-based language generators, effort in development for FY 2024, have the potential to provide timely and useful information to patients, caregivers, clinicians, and researchers. However, despite impressive fluency, these AI language generators often return plausible-sounding responses that contain errors. In a medical context, such errors could lead to inaccurate diagnoses, health hazards, or even death. ARPA-H will develop **novel techniques to enhance the trustworthiness of language generation technologies** for biomedical, health, and patient-related applications to improve their safety, accuracy, and self-awareness. Trustworthiness requires not only high correctness but also the ability to cite sources accurately, to detect errors, and to recognize the limits of its own knowledge.   These research efforts will select use cases that showcase the potential of trustworthy artificial intelligence technology for applications such as interactive patient education, clinical decision support, mental health interventions, patient navigation, faster clinical documentation, and even technology landscape analysis to accelerate ARPA-H's own health program formulation processes. ARPA-H will explore fundamental advances to improve the accuracy of these approaches to improve their fitness for medical applications and reduce incidence of medical errors.

The **Advancing Clinical Trial Readiness (ACTR) initiative,** planned for FY 2024, will explore novel methods to recruit clinical trial participants faster, improve the quality and speed of data collection, and make it easier for people to participate in trials while remaining close to home. Accelerating clinical trials is a core aspect of our agency's success. Currently, it can take months or years to identify patients for a new clinical trial and it is often difficult for those who do not live close to an academic medical center to participate in trials. In addition, the demographics of the

participant population often differ from those who have the disease, which makes it difficult to tell whether treatments are likely to work for women or for under-represented groups. If a treatment is not adequately tested in a particular population, it can lead to worse health outcomes and higher healthcare costs. Advances in clinical trial readiness have the potential to reduce the cost and time to field ARPA-H technologies, and to achieve significant advances in improving the outcomes from clinical trials. In addition, rapid patient identification and patient self-identification can improve opportunities to ensure demographic representation in patient trial participation, which in turn can improve health outcomes and reduce healthcare costs.

The **ADvanced Analysis for Precision cancer Therapy (ADAPT) program**, launching in FY 2024, could also improve cancer treatment. Tumors are well known to change throughout treatment by acquiring or selecting for resistant traits. These opportunistic changes are a key barrier to high treatment response rates. Despite this well-known evolutionary progression in tumors, treatment decisions often rely on biopsies from early in a patient's diagnosis and fail to measure or treat emergent resistance traits as they occur. Rapid advances in approaches such as AI and data-driven analytics have the potential to leverage extensive patient and treatment data to predict complex resistant tumor behaviors. When applied to clinical care, these approaches could enable adaptive treatment regimens that adjust to a tumor's acquired resistance properties as cancer evolves. By advancing personalized treatments, ARPA-H seeks to provide trustworthy, powerful advances in AI systems that provide increasingly accurate predictions of the response to therapies and maximize the chance of overcoming or avoiding resistant traits. To realize this goal, ARPA-H will explore a new clinical trial infrastructure that collects molecularly deep, longitudinal data from patients and allows for iterative sequences of drugs targeting acquired tumor traits as they evolve. This design will also facilitate the integration of biomarkers and therapeutic strategies derived from these new technologies and serves to update clinical care for individual cancer patients. By keeping up with cancer as it changes and evolves, instead of treating it from the starting line, we can give patients a fighting chance.

Over 136 hospitals have closed from 2010 to 2021[1] and by some estimates today, 30% of rural hospitals are at risk for closing, impacting millions of Americans[2]. Due to these closures, patients in rural communities are losing their local health system infrastructure and face high barriers to accessing health care services. To address these challenges, ARPA-H will develop new models for providing care in rural settings and reducing the number of patients that need to travel to doctor visits. The **Platform Accelerating Rural Access to Distributed & Integrated Medical care (PARADIGM) program,** launched in FY 2024**,** will deliver hospital-level care via a multi-purpose Care Delivery Platform (CDP) that is as convenient as telehealth. The CDP will pioneer new developments in point-of-care diagnostics, ensure seamless data exchange between medical devices and electronic health records (EHRs), and offer real-time guidance for medical tasks. The CDP is designed for large-scale deployment by healthcare systems, particularly in rural and resource-limited settings. Achieving this goal will involve multiple parallel work streams including the development of a miniaturized self-shielded CT scanner that achieves >80% reduction in size,

[1] New AHA Report Finds Rural Hospital Closures Threaten Patient Access to Care as Hospitals Face a Range of Rising Pressures | AHA
[2] Rural_Hospitals_at_Risk_of_Closing.pdf (chqpr.org)

weight, and power from standard scanners; software that connects remote medical devices with EHRs; and intelligent task guidance systems to provide real-time, interactive decision support for healthcare workers to perform functions beyond their usual training. These innovations will be integrated into a rugged electric vehicle (EV) platform to create a seamless and efficient environment for advanced and customized care delivery. Health systems will deploy CDPs across the country to evaluate CDP-based care in a broad range of use cases for clinical effectiveness and financial sustainability. This new model will enable health systems to deliver high quality health care to rural communities and areas with health care shortages.

The goal of the **Resilient, Extended, and Automated Cell Therapies (REACT) program,** launched in FY 2024, aims to create new platform technologies that automatically produce and deliver a broad range of therapies from inside the body, to provide enhanced treatments for obesity and diabetes that place far less burden on the patient. Similarly, such an approach could also be extended to cancer immunotherapies to reduce complications during cancer treatments. For example, diabetes and obesity are the primary challenges facing U.S. healthcare, and those who cannot travel to receive regular healthcare are at greater risk for developing costly and debilitating comorbidities, including heart disease and cardiovascular complications, kidney disease, and eye or nerve damage. Techniques that improve treatment quality and consistency of care, while minimizing the number of times that patients visit the doctors are needed, especially in rural areas. The REACT technology aims to greatly expand the range of therapies that could be delivered to best meet an individual's medical needs. Biomolecules that are hard to formulate because of shelf-stability could easily be produced and delivered inside of the patient's body. Additionally, lifelong therapies (e.g., insulin) will no longer be burdensome to regularly administer, leading to overall cost reductions to the US health-care system, including decreased need to travel for doctors' visits and treatments, and improvements in patients' outcomes while reducing the strain on the healthcare system.

The **HEealthcare Rewards to Achieve Improved OutcomES (HEROES)** program, launched in FY 2024, will evaluate reward-based incentives designed to produce improvement in Public Health Outcomes. The program is particularly interested in novel interventions that can rapidly improve health outcomes for everyone living in a geographic area. Reducing the number of patients who require care can relieve pressure on an over-taxed healthcare system and increase the resilience of the population. Population-level efforts to reduce the need for care are sorely lacking in the U.S., which leads to increased system-wide costs and capacity issues and raises the incidence of mortality and morbidity due to illness, disability, and disease. HEROES will investigate approaches to address the following health outcomes: 1) prevention of heart attacks and strokes, 2) avoidance of major pregnancy complications, 3) mitigation in harms associated with alcohol abuse, and 4) reduction of opioid overdoses. These health issues are immense contributors to U.S. health disparities. HEROES will demonstrate a system-level approach toward rigorous, evidence-based disease prevention that prioritizes healthcare over sick care. The health system of the future would thus ameliorate disease and even eliminate health challenges by fostering a more resilient population at the health system level, improving public health and the delivery of health access for all Americans.

To bolster the capacity to mitigate current and emerging health threats, ARPA-H is launching programs to address anti-microbial resistance (AMR). The **Defeating Antibiotic Resistance through Transformative Solutions (DARTS)** project, launched in FY 2023, will build on a highly innovative imaging and culturing system that can individually interrogate billions of bacteria. Bacterial infections are the second leading cause of death worldwide and antimicrobial resistance is increasing while antibiotic discovery lags leading to 5 million deaths in 2019. Diseases that were once treated with a simple oral antibiotic regimen are now becoming difficult or impossible to treat as antibiotic efficacy has dropped due to unintentional overuse for the wrong bacterial strain. Antibiotic resistance represents a huge threat to hospitals and can overwhelm the entire system given the lack of treatment options. This platform will advance to: (1) identify the rare bacteria—the persisters—that lead to antimicrobial resistance and understand the basis for their recalcitrance, (2) identify novel antibiotic peptides and rapidly optimize, and (3) generate a portable device that generates an antibiotic susceptibility profile for infections before the patient leaves the clinic to end mis-prescription of antibiotics. If successful, the bedside instruments developed by DARTS would provide inexpensive and rapid microbial diagnostics to enhance health outcomes for patients with aberrant bacterial infections and reduce stress on the healthcare system.

Transitioning Capabilities: Project Accelerator and Transition Innovation

Program Description

Since the agency's launch, ARPA-H has been executing a strategy to transition successful solutions into the commercial market or other appropriate endpoints. A key component of that strategy is to "work backwards," which means to start with the end in mind during the solution design stage when it is easier and less expensive to pivot. This requires a dedicated team to provide transition-focused assistance on technical areas and milestones during program concept design. Expertise spans from science, medicine, markets, regulatory, human-centered design, and program management. Accordingly, ARPA-H established a Project Accelerator and Transition Innovation team, which **increases the probability that ARPA-H funded health technologies will reach Americans by identifying barriers and providing transition and commercialization capabilities to program managers and performers.** The Project Accelerator and Transition Innovation team has positively influenced almost every ARPA-H technical program and has spearheaded several transition-focused R&D efforts for the agency.

The Project Accelerator and Transition Innovation capabilities thrusts include:

1) **Building transition-ready programs by de-risking solutions from program design through performance.** This thrust mainly focuses on systems-level issues like regulatory frameworks, reimbursement/payment, and market dynamics. Related capabilities include:

   - Experts in Residence (XIR) Program – Using external, recognized transition/commercialization experts to identify and solve for commercialization blind spots of ARPA-H PMs and programs. These experts help shape programs and prevent duplication with government and the private sector. In a PM's first few weeks, an XIR is assigned and serves as a peer mentor to the PM. The XIR also has access to the entire network of XIRs and tools to ensure PMs can incorporate a wide range of expertise into their programs.
   - Regulatory & Reimbursement Support – Conducting efforts to demystify and assist in navigation of regulatory and reimbursement processes.
   - Due Diligence and Landscape Analyses – Pursuing due diligence and intellectual property analyses, commercialization landscape to understand a particular technology, competitive landscape to understand key players in the arena, and the state of science.
   - Small Business Program – Providing small businesses funding opportunities to possess the expertise necessary to acquire innovative approaches for revolutionary advances in science, technology, or systems leading to developments that contribute toward the agency's mission. This program leverages the typical Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) program in two ways. First, topics are chosen by PMs to seed future program ideas and/or fill gaps in existing programs. This helps to build the portfolio of agency projects on a smaller scale before the larger dollars of a full-scale program (derisking on a topical level). Second, each SBIR/STTR awardee receives a needs assessment and can obtain an

entrepreneur in residence (EIR) who works closely with performers to get solutions closer to market (derisking on an operational level).

SBIR/STTR Topics:

FY 2023:
ARPA-H 01 - Novel telehealth instruments for assessing pediatric well-being.
ARPA-H 02 - Microneedle-based patches and digital patch interfaces for remote and real-time transdermal drug delivery and chronic disease management.
ARPA-H 03 – Robotics for autonomous soft tissue surgery.
ARPA-H 04 – Intra-operative contrast agents.

FY 2024:
ARPA-H 01 - Inexpensive plant-based manufacturing of viral vectors for gene therapies
ARPA-H 02 - LymphoLab ProDiscover Kit
ARPA-H 03 - Continuous Monitoring of Vascular health using Smart Biomimetic Implantables
ARPA-H 04 - Personalized medicine platform for predicting response to immunotherapy
ARPA-H 05 - Saving Baby Hearts: Fully Autonomous Neonatal Echocardiography for the Diagnosis of Critical Congenital Heart Disease
ARPA-H 06 - Improving Identity and Access Management with Clinical Context

2) **Creating meaningful bi-directional communication between ARPA-H and stakeholders in the health ecosystem.** The Project Accelerator and Transition Innovation team is actively developing a health ecosystem to enable identification of transition partners, end users, and beneficiaries. Each year, the agency expects to engage with hundreds of patient and advocacy groups. As an Agency, ARPA-H values broad public participation and community engagement in regulatory and civic processes and in R&D. To date, the Agency has met with hundreds of entities, including patient advocacy groups, universities, and private companies to explain the ARPA-H model and listen to their recommendations for the agency. This is a major driver of how we amplify the ARPA message and focuses primarily on the human level, aiming to access and understand the varied experiences of different. This includes patients and beneficiaries of solutions. This bi-directional understanding is crucial for ARPA-H to build capabilities that resonate with the American people.

In addition, the Project Accelerator and Transition Innovation team is conducting in person engagements with other key partners such as other government agencies, investors, large and small businesses, and universities. An important line of effort is to build partnerships with Historically Black Colleges and Universities (HBCUs) and Minority Serving Institutions (MSIs)— to engage and intentionally source a diverse and informative pool of candidates to source PMs, R&D performers, and beneficiaries of ARPA-H solutions. Capabilities in this area include:
- Ecosystem Activities & Speaking Opportunities: Broad, in-person engagements where ARPA-H leaders explain the ARPA-H model and mission and build connections.

- Network on Demand: A self-service platform for ARPA-H PMs and others to access key external stakeholders and ensure de-duplication of efforts.
- Design Services: Capturing the needs and perspectives of expected agency beneficiaries using design research tools and practices.
- In-Person Discovery Trips: Targeted, deep dive trips with small groups of ARPA-H technical staff to deepen perspectives.

3) **Designing and executing the ARPA-H Health Innovation Network (ARPANET-H).** In October 2023, the Project Accelerator and Transition Innovation team launched ARPANET-H, to connect a fragmented health ecosystem through projects, events, and democratized learning. Using a "hub and spoke model", ARPANET-H's two hubs and vast network of spokes, provide an opportunity for a variety of projects and components of programs to be launched in relevant geographies and with diverse populations. Hubs and their associated "spokes" or satellite sites support the diverse portfolio of ARPA-H projects and programs. To ensure maximum national impact, ARPANET-H has spokes in all 50 states.

ARPANET-H R&D activities can take a few forms. One high value activity is a "sprint". ARPA-H kicked off its first sprint in January 2024—the ARPA-H Sprint for Women's Health. The agency expects to run sprints through the ARPANET-H on a quarterly basis (approximately). The sprints will target "white space", that is, challenges identified by ARPA-H that are unmet needs for Americans that are not already being addressed in ARPA-H's portfolio.

Through a "sprint", ARPA-H galvanizes the innovator, investor, researcher, and patient advocate communities to proactively address health-related challenges, raise awareness, and spur innovation with two major funding opportunity tracks. The two funding opportunity tracks aim to foster transformative R&D efforts from early-stage research "Spark" to later-stage development "Launchpad", that impact and improve health outcomes. With the two funding opportunity tracks, ARPA-H aims to lower barriers of entry for a diverse range of participants, with a simplified submission process of an abstract followed by a pitch session.

Each sprint is designed similarly and follows a reusable process. After ARPA-H identifies the challenge, it identifies leading experts from across the health ecosystem to validate the white space, and then it convenes events with experts and program managers to formulate the problems.

Once specific problems have been identified, ARPA-H has designed a streamlined proposal and funding process for potential performers, especially targeting those that do not typically conduct business with the government. This includes a request for solutions—a funding opportunity based on the insights developed during the first stages of the sprint—with a low-lift abstract proposal process, followed by an in-person, private-sector style pitch for top submissions to select proposals for funding. After award, projects are managed similarly to all ARPA-H programs—with active management and rigorous milestones that buy down technical, market, and business model risk. Successful solutions can then be launched—and an appropriate transition partner will sustain the solutions developed from ARPA-H funded projects.

Another high-value ARPANET-H activity is joint projects with other federal partners. For example, in partnership with the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), ARPA-H is developing a Data Marketplace to make regulatory-ready medical imaging data available to researchers and AI/ML developers. ARPANET-H is key

to this effort. It will enable FDA/CDRH and ARPA-H to collect information at scale from spokes in the network about what data will be most valuable, how researchers will use the data, and how to overcome barriers to sharing it. ARPANET-H is also a vehicle for gauging the public's willingness to accept / use the marketplace, and to identify early-adopters that will be key in its launch. Using ARPANET-H, the project will collect data from more than 150 data users, data managers, and data providers, and special attention is placed on collecting input from the entire American healthcare ecosystem

ARPANET-H is split into two separate, but related networks.

- The Customer Experience (CX) network drives user testing, adoption, access, and trust of ARPA-H projects. This hub also takes a proactive approach to enhance clinical trials, reach diverse and representative patient communities and populations, and capture outcomes data for future research.
- The Investor Catalyst (IC) network assists ARPA-H programs and projects in navigating the complexities of the business, transition, and regulatory landscape and provides resources to help performers in all parts of the county bring their ideas to market.

ARPANET-H is bringing impact to the country and to ARPA-H. The network is engaging spokes with locations in all 50 states, bringing access to capabilities for PMs and performers. Some specific examples of the power of this network include:

Reach of the network. As of February 26, 2024, the CX network comprised 288 spokes in 39 states by HQ location; includes 48 institutions of higher education, 59 nonprofits, 37 for-profits; 134 small businesses/start-ups; and the IC network comprised 149 spokes in 44 states by HQ location; includes 28 IHEs, 57 nonprofits, 58 for-profits; 47 small businesses/start-ups.

Sprint for Women's Health. The IC hub was leveraged to convene experts in women's health from around the country to enable problem formulation. Problems generated from the convening are being finalized for a request for solutions, for which the IC Hub is running the solicitation process. As of February 26, 2024, only a few days after the Proposers Day announcement, 1,050 people were registered for Proposers Day.

ACTR Network Survey. The CX network initiated a survey to its network to help shape a potential new Advancing Clinical Trials Readiness initiative. It received 151 responses in 46 days, from a variety of organization types covering 31 states, and with catchment areas serving the entire US.

HEROES Network Activation. The HEROES program pulsed the network to engage organizations of interest to participate in events to shape the program—including health accelerators, outcome buyers, and at-risk investors. Participants engaged in roundtable discussions focused on questions that informed critical components of the HEROES program's structure and execution. The IC Hub provided matchmaking services during and after Proposers Day and secured speakers to address investment and outcome buyer perspectives.

With ARPA-H's transitioning capabilities, the agency will have the opportunity to catapult basic and applied research that supports American innovation enterprise -- creating solutions that provide sustainability and equitable health solutions for all.

Budget Request

The FY 2025 President's Budget request for ARPA-H is $1.5 billion, same level as the FY 2023 Enacted. The FY 2025 budget request will allow ARPA-H to continue program investments that address specific, urgent, and challenging problems in health and ARPA-H's business operations, which drive the agency forward. This funding will support ARPA-H's mission to accelerate better health outcomes for everyone through these program investments:

- *Accelerating Foundational Advances in Medical Research.* Expand what is technically possible by developing approaches that bring radically new insights and paradigms. This focus area targets innovative tools, technologies, and platforms that can apply to a broad range of diseases that affect large populations, rare diseases, or diseases with limited treatment options.

- *Improving Health Care Access and Affordability.* Reach everyone quickly by addressing challenges that include geography, distribution, manufacturing, data and information, and economies of scale to create programs that improve healthcare access and affordability.

- *Breakthrough Capabilities to Mitigate the risk of Disease Onset and Progression.* Keep people from becoming patients by creating new capabilities to identify and characterize disease risk, reduce comorbidities, and promote treatments and behaviors to improve health and wellness, reducing the likelihood of medical intervention or accelerating recovery and regeneration capabilities.

- *Driving Advances in Health Systems.* Create capabilities, develop mechanisms, and accelerate system integrations to enhance health ecosystem stability and reliability to persevere through crises, from the molecular to the societal scale, explore human-centric designs, and foster health system resilience to pandemics, natural disasters, injuries, cyber-attacks, and financial challenges.

- *Transitioning high impact technologies into the commercial market and to other endpoints and end users.* Increase the probability that ARPA-H funded health technologies reach all Americans by identifying barriers to transition and then understanding and developing capabilities to lower those barriers and providing transition and commercialization services to program managers and performers. Increase the odds that solutions attract outside investment and customers, so breakthroughs reach the American people.

Five Year Funding Table

FY 2021	$	-
FY 2022	$	1,000,000,000
FY 2023 Final	$	1,500,000,000
FY 2024 CR	$	1,500,000,000
FY 2025 President's Budget	$	1,500,000,000

Accomplishments

ARPA-H demonstrated remarkable progress in achieving pivotal congressional objectives. Specifically, P.L. 117-328 directed ARPA-H initiate cutting-edge R&D programs, establish three strategic locations, and engage in collaborative efforts with other agencies – specifically with the Food Drug Administration (FDA). ARPA-H has not only met but exceeded these expectations by launching significant R&D programs, establishing a nationwide network, and building foundational relationships with key federal partners. These goals not only signal a positive outlook on the agency's potential impact in the biomedical arena but also underscore the significant accomplishments achieved by ARPA-H to date, showcasing its commitment to advancing groundbreaking initiatives.

Program Launches:

At rapid pace and with a high-risk, high reward approach, ARPA-H has launched transformative programs and projects that contribute to cutting-edge advancements in biomedical research. Each of these programs and projects were selected by the ARPA-H Director and Agency team. After careful, methodical examination, these efforts were determined to meet the Agency's key principles of scalable, transformative research that provides health solutions to diverse patient populations. In addition, ARPA-H conducted thorough due diligence to ensure these new program and project launches were not duplicative of efforts in other federal and commercial activities.

The R&D programs funded by ARPA-H impact cancer and other diseases, conditions, and disruptive health systems. Current programs include Novel Innovations for Tissue Regeneration in Osteoarthritis (NITRO), Precision Surgical Interventions (PSI), Resilient Extended Automatic Cell Therapies (REACT), and Antigens Predicted for Broad Viral Efficacy through Computational Experimentation (APECx). Most recent programs launched include Platform Accelerating Rural Access to Distributed & InteGrated Medical care (PARADIGM), Transplantation of Human Eye Allografts (THEA), and Health Care Rewards to Achieve Improved Outcomes (HEROES). Each program showcases ARPA-H's commitment to innovation, with unique solutions poised to reshape biomedical landscapes and improve patient outcomes. For additional information on ARPA-H programs, see the ARPA-H website.

Program Manager Hiring:

ARPA-H significantly strengthened its team by onboarding 14 program managers in less than 12 months, exceeding the initial goal of 11. In addition, the Agency selected all 4 Mission Office Directors, providing the oversight, direction and focus on R&D programs necessary to catapult expeditious delivery of unique R&D solutions. This quick-start, strategic expansion not only bolstered the agency's unique capabilities but also emphasized a commitment to diverse expertise in propelling its' initiatives forward.

Cancer Moonshot:

ARPA-H made substantial progress in advancing the Cancer Moonshot initiative through groundbreaking projects. These projects include Advancing Clinical Trial Readiness (ACTR), the ARPA-H Biomedical Data Fabric (BDF) Toolbox, Curing the Uncurable via RNA-Encoded Immunogene Tuning (CUREIT), Cell Therapies for Neuroinflammation and Neurodegeneration

(CT-NEURO), Targeted Hybrid Oncotherapeutic Regulation (THOR), Mapping the Cancer and Organ Degradome Atlas (CODA), Revolutionizing the Oral Route (REO), and Programmable Scalable Therapeutics for Immune-Directed Cancer-Killing (SPIKEs). These projects collectively showcase ARPA-H's immediate dedication to advancing cancer research and treatment, jumpstarting the Agency's alignment with Cancer Moonshot initiative goals.

ARPANET-H:

To ensure the scalability of its programs and to create opportunities for breakthrough capabilities that achieve health outcomes for everyone, ARPA-H designed ARPANET-H. This "hub and spoke" model enables the Agency to present solutions that are accessible, tangible, and measurably better, regardless of location. With ARPANET-H, the Agency established three "hubs", each with a define role and location – Customer Experience (Dallas, TX), Investor Catalyst (Cambridge, MA), and Stakeholder and Operations (Washington, DC) – that establishes a health innovation network through their respective spokes. With ARPA-H funding, these hubs and spokes will support the best and brightest ideas across the country, to catalyze game-changing breakthroughs in science and medicine that improve health outcomes.

By the end of January 2024, ARPANET-H already contained over 400 spokes with locations in all 50 states. By utilizing this hub and spoke model, ARPA-H expanded the call for a minimal three location presence, creating a network representing the diversity of people, settings, and capabilities that encompass the American health ecosystem. Through ARPANET-H, the Agency is creating efficiencies that could not otherwise be achieved - reaching patients, providers, and other stakeholders quickly and building a foundation for an ambitious 50 state network to support health innovation across the entire Nation.

Engagements:

ARPA-H achieved a significant milestone in 2023 by spearheading a Request for Information (RFI) initiative aimed at fostering collaboration with the FDA. The Agency currently hosts quarterly meetings to ensure transparency and coordination on ARPA-H and FDA efforts and to strategize on mutual benefit engagements. Since its inception, ARPA-H has actively collaborated with numerous federal agencies, both within and outside the HHS umbrella. These partnerships aim to establish enduring governmental collaborations that drive greater innovation, leading to breakthrough solutions not achievable solely through ARPA-H efforts. In addition, ARPA-H launched several Partnership Intermediary Agreements (PIA) to streamline pathways for robust public-private partnerships. With these PIAs, ARPA-H will provide a base for ensuring the commercialization of agency solutions into the marketplace.

Global Initiatives:

ARPA-H is actively seeking to pursue initiatives that aim to maintain global leadership in science and innovation. The Agency seeks to catalyze the U.S. and global innovation ecosystems in the pursuit of novel solutions to the most pressing challenges in human health and health care. In 2024, ARPA-H is accelerating international collaborations that will enhance the impact of agency's initiatives on a global scale and advance U.S. leadership in science, technology, and innovation. ARPA-H is establishing and nurturing partnerships with foreign governments, research institutes, companies, non-governmental organizations, and other key stakeholders to drive innovation in biomedical research both in the U.S. and abroad.

Performance Measures

Key Outputs and Outcomes

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2024 Target	FY 2025 Target	FY 2025 Target +/- FY 2024 Target
1.0: Number of Program Managers Onboard	N/A	N/A	50	
1.1: Time between Science and Technology Board program approval and Congressional Notification of program launch	N/A	N/A	Baseline	
1.2: 60% of discretionary funds obligated within the first year of appropriation	N/A	N/A	60%	
1.3: Utilization Rate by programs of Customer Experience and Investor Catalyst Hubs	N/A	N/A	Baseline	
1.4: Tools developed to expand availability of affordable, relevant, and broadly implementable cyber and infrastructure resilience tools to health system entities	N/A	N/A	Baseline	
1.5: Tools developed to increase accessibility and information sharing of healthcare, biomedical research, and clinical trials data and evidence for researchers, patients, and providers	N/A	N/A	Baseline	

Section IV: Supporting Exhibits

Budget Authority by Object Classification
Advanced Research Projects Agency for Health

(Dollars in thousands)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Personnel compensation:				
Full-time permanent (11.1)	$ 6,292	$ 15,914	$ 21,192	$ 14,900
Other than full-time permanent (11.3)	$ 3,077	$ 7,781	$ 10,362	$ 7,285
Other personnel compensation (11.5)	$ 299	$ 756	$ 1,006	$ 708
Subtotal personnel compensation	**$ 9,667**	**$ 24,451**	**$ 32,560**	**$ 22,892**
Civilian benefits (12.1)	$ 3,394	$ 8,584	$ 11,430	$ 8,036
Total Pay Costs	**$ 13,061**	**$ 33,035**	**$ 43,990**	**$ 30,929**
Travel and transportation of persons (21.0)	$ 624	$ 624	$ 624	$ 0
Transportation of things (22.0)	$ 6	$ 6	$ 6	$ -
Rental payments to GSA (23.1)		$ -	$ -	$ -
Rental payments to Others (23.2)	$ 93	$ 1,932	$ 2,733	$ 2,640
Communication, utilities, and misc. charges (23.3)	$ 50	$ 50	$ 50	$ -
Printing and reproduction (24.0)	$ 0.6	$ 0.6	$ 0.6	$ -
Other Contractual Services:				
Advisory and assistance services (25.1)	$ 689	$ 689	$ 689	$ -
Other services (25.2)	$ 183,188	$ 39,966	$ 28,210	$ (154,978)
Purchase of goods and services from government accounts (25.3)	$ 70,312	$ 70,312	$ 70,312	$ -
Operation and maintenance of facilities (25.4)	$ 14	$ 14	$ 14	$ -
Research and Development Contracts (25.5)	$ 734,169	$ 855,577	$ 855,577	$ 121,408
Operation and maintenance of equipment (25.7)	$ 450	$ 450	$ 450	$ -
Subtotal Other Contractual Services	**$ 988,821**	**$ 967,008**	**$ 955,252**	**$ (33,569)**
Supplies and materials (26.0)	$ 1,397	$ 1,397	$ 1,397	$ -
Equipment (31.0)	$ 1,520	$ 1,520	$ 1,520	$ -
Grants, subsidies, and contributions (41.0)	$ 494,423	$ 494,423	$ 494,423	$ -
Interest and dividends (43.0)	$ 5	$ 5	$ 5	$ 0
Total Non-Pay Costs	**$ 1,486,939**	**$ 1,466,965**	**$ 1,456,010**	**$ (30,929)**
Total Budget Authority by Object Class	**$ 1,500,000**	**$ 1,500,000**	**$ 1,500,000**	**$ (0)**

Salaries and Expenses Table
Advanced Research Projects Agency for Health

(Dollars in thousands)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Personnel compensation:				
Full-time permanent (11.1)..............................	$ 6,292	$ 15,914	$ 21,192	$ 14,900
Other than full-time permanent (11.3)............................	$ 3,077	$ 7,781	$ 10,362	$ 7,285
Other personnel compensation (11.5).............................	$ 299	$ 756	$ 1,006	$ 708
Subtotal personnel compensation.............................	**$ 9,667**	**$ 24,451**	**$ 32,560**	**$ 22,892**
Civilian benefits (12.1)...................................	$ 3,394	$ 8,584	$ 11,430	$ 8,036
Total Pay Costs	**$ 13,061**	**$ 33,035**	**$ 43,990**	**$ 30,929**
Travel and transportation of persons (21.0)....................	$ 624	$ 624	$ 624	$ 0
Transportation of things (22.0)..	$ 6	$ 6	$ 6	$ -
Rental payments to Others (23.2)..................................	$ 93	$ 1,932	$ 2,733	$ 2,640
Communication, utilities, and misc. charges (23.3).........	$ 50	$ 50	$ 50	$ -
Printing and reproduction (24.0).....................................	$ 0.6	$ 0.6	$ 0.6	$ -
Other Contractual Services:				
Advisory and assistance services (25.1)........................	$ 689	$ 689	$ 689	$ -
Other services (25.2)...	$ 183,188	$ 39,966	$ 28,210	$ (154,978)
Purchase of goods and services from government accounts (25.3)	$ 70,312	$ 70,312	$ 70,312	$ -
Operation and maintenance of facilities (25.4)................	$ 14	$ 14	$ 14	$ -
Research and Development Contracts (25.5)....................	$ 734,169	$ 855,577	$ 855,577	$ 121,408
Operation and maintenance of equipment (25.7).............	$ 450	$ 450	$ 450	$ -
Subtotal Other Contractual Services.....................	**$ 988,821**	**$ 967,008**	**$ 955,252**	**$ (33,569)**
Supplies and materials (26.0)..	$ 1,397	$ 1,397	$ 1,397	$ -
Total Non-Pay Costs	**$ 990,991**	**$ 971,017**	**$ 960,062**	**$ (30,929)**
Total Salary and Expense	**$ 1,004,052**	**$ 1,004,052**	**$ 1,004,052**	**$ (0)**
Direct FTE	**47**	**112**	**137**	**90**

Detail of FTE[1]

	2023 Actual Civilian	2023 Actual Total	2024 Est. Civilian	2024 Est. Total	2025 Est. Civilian	2025 Est. Total
Director's Office						
Direct:	8	8	14	14	14	14
Total:	8	8	14	14	14	14
Chief Information Officer						
Direct:	1	1	7	7	8	8
Total:	1	1	7	7	8	8
Acquisition & Contracting Office						
Direct:	6	6	18	18	20	20
Total:	6	6	18	18	20	20
Strategic Resource Office						
Direct:	12	12	20	20	20	20
Total:	12	12	20	20	20	20
Comptroller Office						
Direct:	8	8	16	16	17	17
Total:	8	8	16	16	17	17
Project Accelerator Transition Innovation Office						
Direct:	1	1	6	6	6	6
Total:	1	1	6	6	6	6
Engagement & Communications Office						
Direct:	6	6	4	4	5	5
Total:	6	6	4	4	5	5
Legislative & Governmental Affairs Office						
Direct:	1	1	3	3	3	3
Total:	1	1	3	3	3	3
Director's Office-Special Projects						
Direct:	2	2	5	5	5	5
Total:	2	2	5	5	5	5
Health Sciences Focus Area						
Direct:	0	0	8	8	11	11
Total:	0	0	8	8	11	11
Proactive Health Focus Area						
Direct:	0	0	3	3	7	7
Total:	0	0	3	3	7	7
Resilient Systems Focus Area						
Direct:	1	1	7	7	12	12
Total:	1	1	7	7	12	12
Scalable Solutions Focus Area						
Direct:	0	0	1	1	9	9
Total:	0	0	1	1	9	9
OPDIV FTE Total	**47**	**47**	**112**	**112**	**137**	**137**
Average GS Grade						
FY 2021	N/A					
FY 2022	N/A					
FY 2023	13/02					
FY 2024	15/10					
FY 2025	15/10					

Detail of Positions
Advanced Research Projects Agency for Health

(Dollars in thousands)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget
Executive level I			
Executive level II	1	1	1
Executive level III			
Executive level IV	2	2	2
Executive level V			
Subtotal Executive Level Positions	3	3	3
Total - Exec. Level Salaries	$ 439,566	$ 614,821	$ 638,789
Subtotal ES positions	3	$ 3	$ 3
Total - ES Salary	$ 439,566	$ 614,821	$ 638,789
GS-15	19	21	21
GS-14	29	32	32
GS-13	9	12	12
GS-12	4	5	5
GS-11	2	2	2
GS-9	1	1	1
Subtotal	64	73	73
Total - GS Salary	$ 5,485,902	$ 11,131,232	$ 12,401,085
Ungraded			
Administratively Determined	26	50	71
T42	1	1	1
Subtotal	27	51	72
Total - Ungraded salaries	$ 3,398,707	$ 11,322,632	$ 18,151,236
Average ES level	1	2	2
Average ES salary	$ 146,522	$ 204,940	$ 212,930
Average GS grade	13.2	15.1	15.1
Average GS salary	$ 85,717	$ 152,483	$ 169,878
Average Special Pay categories			
Administratively Determined	$ 116,245	$ 218,830	$ 250,195
T42	$ 376,339	$ 381,138	$ 387,397

Cybersecurity
Advanced Research Projects Agency for Health

(Dollars in millions)

Cyber Category	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Cyber Human Capital..	--	$ 0.03	$ 0.03	$ +0.030
Planning Roles and Responsibilities......................................	--	--	--	--
Sector Risk Assessment, Management, and Operations........	$ 8.490	$ 11.460	$ 12.030	$ +3.540
Sector Coordination	--	--	--	--
Other NIST CSF Capabilities:				
Detect..	$ 0.21	$ 2.160	$ 2.260	$ +2.050
Identify..	$ 0.50	$ 0.43	$ 0.45	$ -0.050
Protect...	$ 0.09	$ 7.590	$ 7.970	$ +7.880
Recover..	--	--	--	--
Respond...	$ 0.45	$ 0.22	$ 0.23	$ -0.220
Total Cyber Request...	**$ 9.740**	**$ 21.890**	**$ 22.970**	**$ 13.230**
Technology Ecosystems (non-add)...........................	--	--	--	--
Zero Trust Implementation (non-add)........................	--	*$ 2.000*	*$ 2.500*	*$ 2.500*