ARPA-H

Fiscal Years 2024–2026

Advanced Research Projects Agency for Health Strategic Plan

ARPA-H MISSION

Accelerate better health outcomes for everyone.

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Letter from the Director

Dear Patients, Partners, and Visionaries,

It is with great excitement and a profound sense of purpose that I present the inaugural Advanced Research Projects Agency for Health (ARPA-H) Strategic Plan. Since our establishment in March 2022, ARPA-H has embarked on a mission of unparalleled significance — to enhance health outcomes for every individual, leaving no one behind.

At the core of our vision lies an unwavering commitment to supporting groundbreaking solutions to society's most daunting health challenges. By doing so, we are laying the foundation for the next generation of life-saving treatments and cures, poised to elevate the health and well-being of Americans and the globe.

ARPA-H is a catalyst for transformation in the health ecosystem. We operate at the forefront of scientific advancement, nurturing high-risk, high-reward programs that have the potential to reshape the very fabric of health research and innovation and usher in cures that were previously thought to be unattainable. Our resolve is unyielding and our ambition boundless.

As we embark on this transformative journey, we anticipate outcomes that include pioneering novel technologies to address debilitating chronic diseases, accelerating progress in the fight against cancer, advancing gene-encoded technology, addressing antimicrobial resistance, improving population wellness, reducing health care provider cyber vulnerabilities, and enhancing the accuracy and cost-effectiveness of artificial intelligence in health care, among many others.

The objectives delineated in this strategic plan serve as the cornerstone of our program planning and budget execution. Together, they create a holistic framework for achieving the agency's mission. As we move forward, ARPA-H remains committed to nurturing innovation, fostering collaboration, and relentlessly pursuing solutions that will redefine the landscape of health care.

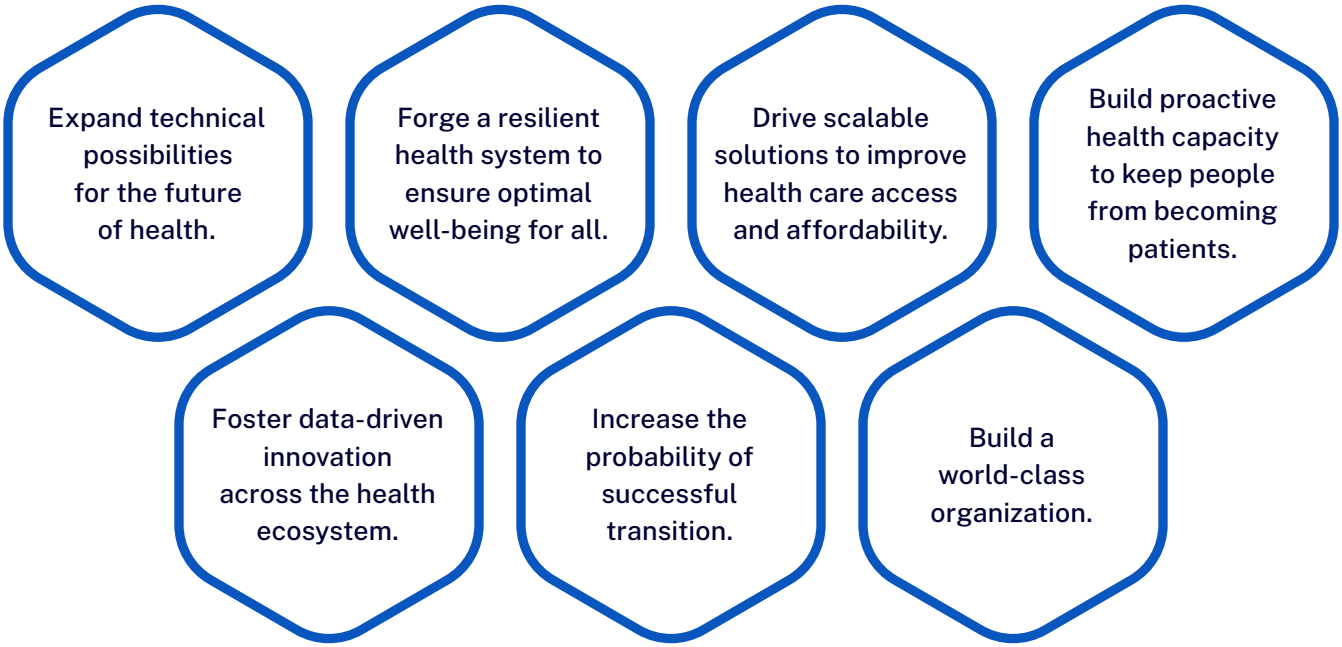
I extend my heartfelt gratitude to the valued patients, partners, and visionaries who share our vision for a healthier world. Together, we will unlock new frontiers in health research and innovation, where bold ideas become tangible realities.

Sincerely,

Renee Wegrzyn, Ph.D., Director,
Advanced Research Projects Agency for Health

Overview

The Advanced Research Projects Agency for Health (ARPA-H) was established in March 2022 to improve health outcomes for everyone. By supporting the development of high-impact solutions to society's most challenging health problems, ARPA-H aims to create the next generation of lifesaving treatments and cures to improve the health and well-being of all Americans. ARPA-H will operate at the forefront of scientific advancement, catalyzing groundbreaking innovation and nurturing high-risk, high-reward programs with the potential to transform the health ecosystem. This *FY24 – FY26 ARPA-H Strategic Plan*[1] sets the Agency's inaugural goals as follows:



Through implementation of this strategy, ARPA-H will address the most urgent challenges in the health ecosystem, including issues such as the escalating rates of chronic diseases, inequitable access to high-quality health care, vulnerabilities in data security and privacy, prevention and treatment strategies for cancer, novel interventions for neurodegenerative diseases, strategies to improve the mental health and substance use disorder crises, the continued need for pandemic preparedness, and the rise of antimicrobial resistance, among others.

1 This strategic plan fulfills the requirement in section 499A(l) of the Public Health Service Act (PHSA), as added by section 2331(a) of the Consolidated Appropriations Act, 2023 (P.L. 117-328), to describe how ARPA-H will carry out investments each fiscal year in the following 3-year period.

ARPA Model for Health

ARPA-H is a newly established federal health research and development (R&D) organization uniquely positioned to further the U.S. government's efforts to maintain global leadership in science and innovation. ARPA-H is modeled after several advanced research project agencies (ARPAs) and applies 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.

ARPA-H will tackle longstanding problems in the health ecosystem while also remaining agile enough to respond to emerging issues. The agency will do so by developing new tools, technologies, and approaches to collaboration among federal, state, and local government officials, health care providers, researchers, communities, both domestic and international. ARPA-H embraces novel public/private partnership arrangements 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.

Investment Approach

The goals and objectives identified in this strategic plan will drive program planning and budget execution to create a holistic approach to achieving the agency's mission. ARPA-H will prioritize investments based on scientific opportunity, potential impact, and applications that may address areas of currently unmet need for the American people.

Like other ARPAs, ARPA-H employs an active portfolio development approach that identifies programs based on clearly defined problems in the health ecosystem, led by the expertise of ARPA-H program managers (PMs). This distinguishes ARPA-H from other federal health R&D organizations in that ARPA-H does not have a pre-ordained nor passive portfolio requirements approach. ARPA-H will manage a diversified and balanced portfolio of investments in areas such as platform technologies that provide population-level solutions, technology innovations that ensure accessibility and affordability to meet the needs of all Americans.

Together, advances in several areas will propel equitable health care access and treatment distribution across all socio-economic populations. ARPA-H will fund two general categories of efforts: 1) specific programs, and 2) single projects. Specific programs are large efforts that include multiple funded 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 Broad Agency Announcement (open BAA). While single projects are still led, managed, and directed by the PM, the initial concept idea is typically something that is brought to ARPA-H through the open BAA rather than the direct solicitation of concepts from specific programs. The specific amounts of portfolio investments are determined when the final performing teams are selected, ensuring best use of government funds.

Guiding Principles

These principles help direct the agency's actions, decisions, and behavior. They shape ARPA-H culture, inform policies and practices, and guide employees in achieving the mission and objectives.

Equity: ARPA-H is committed to advancing equity within the agency and throughout its technical portfolio, including with respect to race, ethnicity, gender/gender identity, sexual orientation, disability, geography, employment and insurance status, and socioeconomic status. The ARPA-H workforce represents diverse backgrounds and perspectives, which is essential to fostering a creative, inclusive culture and developing policies, practices, and programs that sustain an ongoing focus on equity. ARPA-H programs are required to establish plans to address potential misuse and disparities in health outcomes, affordability, and accessibility prior to launch. The programs push boundaries to ensure that their advancements benefit everyone, especially those who have historically been underrepresented in biomedical research and development efforts.

Accessibility and Affordability: Through program design, contract structures, activation of a nation-wide health innovation network, early patient and community engagement, and a focus on transition pathways, ARPA-H will prioritize making solutions accessible and affordable to those in need.

Clear Pathways to Success: ARPA-H de-risks solutions so they may transition successfully to advanced developers and downstream funders following ARPA-H investment. Every ARPA-H effort considers possible transition pathways at inception. Transition pathways may include, but are not limited to, a health care system or provider network that will deploy the licensed technology through their care network; a venture capital-backed emerging company with demonstrated commitment to the technology's domain area; an additional government agency that will adopt the solution; or an established company or non-profit with existing infrastructure for development, sales, and distribution.

Problem Focused: The ARPA-H model is centered around solving specific, high-risk, high-reward problems with technical and programmatic rigor over finite amounts of time. This problem-focused approach aims to address critical challenges in the health sector, emphasizing precision and effectiveness.

Agility and Adaptability: ARPA-H emphasizes iterative development and rapid prototyping to allow for quick adaptation and refinement of projects based on real-world results and feedback from patients and caregivers — ARPA-H's primary customers. ARPA-H also has flexible awards processes to pivot and adjust project funding based on emerging trends, breakthroughs, and evolving needs.

Program Manager-Driven: In the ARPA-H framework, Program Managers (PMs) are integral drivers of innovation. These term-limited health ecosystem visionaries bring together creativity, determination, and proven expertise. They work with unique urgency, efficiency, and speed, adopting a bottom-up approach to tackle some of the most complex issues in health care today.

Cross-Disciplinary Collaboration: ARPA-H promotes collaboration across diverse technical fields and market sectors. By encouraging experts from varied domains to work together, ARPA-H fosters a creative exchange of ideas that can lead to innovative solutions, including from non-traditional sources.

Accountability: ARPA-H places a strong emphasis on measurable outcomes and milestones. Projects are closely monitored, and funding is tied to achieving specific goals, ensuring that taxpayer investment leads to tangible results.

By adhering to these core principles, ARPA-H commits to being a dynamic and forward-thinking agency that actively drives innovation, accelerates research breakthroughs, and positions itself as a pivotal player in advancing health-related technologies and solutions.

AGENCY GOALS

Goal 1: Expand Technical Possibilities for the Future of Health

ARPA-H strategically invests in foundational technologies that are poised to revolutionize the future of health. Current development of platform technologies to address human diseases faces challenges in integrating diverse disciplines, such as biology, engineering, and data science, to create comprehensive solutions.

ARPA-H will focus on removing obstacles that inhibit innovation and explore new ideas and methods to accelerate progress. These ideas and methods will transcend specific disease boundaries, catalyze breakthroughs across a wide spectrum of health challenges, and address critical hurdles to ensure scalability, interoperability, and regulatory compliance across multidisciplinary platforms.

Goal 1 Objectives

1.1 **Catalyze research toward platform technologies:** Develop new tools and technologies for detection, manufacturing, and drug development, and envision new and "programmable" drug modalities.

1.2 **Accelerate development of novel tools to enable a new future of health care:** Establish novel methods for targeted drug delivery, new disease-agnostic drug paradigms, cell and gene-based therapies, innovations in organ transplantation, and agile technologies designed to facilitate the discovery, characterization, and production of preventatives and therapeutics.

1.3 **Lead creation of entirely new paradigms:** Develop technologies that can easily reconfigure to treat multiple diseases, accelerate the ability to discover new therapies, and reduce off-target effects of existing therapies.

Goal 2: Forge a Resilient Health Ecosystem to Ensure Optimal Well-Being for All

ARPA-H will address systemic challenges across the health landscape by investing in cutting-edge technologies that address long-standing gaps in the quality, efficacy, and availability of care. Aspects of today's health systems remain fragile due to systemic challenges, which include rising health care costs, inadequate health care coverage for significant populations, outdated infrastructure, and health disparities among different demographic groups. Acute challenges, such as hospital closures, supply chain disruptions, staffing shortages, cyberattacks, 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.

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.

Goal 2 Objectives

2.1 **Empower patients, providers, and communities through transformational innovation:** Develop user-centric digital health tools, platforms, technologies, and intervention models that actively manage prevention, diagnosis, treatment, and care across the health continuum. Such advances will enable personalized care, real-time monitoring, evidence-based approaches, and informed decision-making. Ultimately, high-quality care depends on the combination of people and technology working seamlessly together to enhance human performance, communication, and care for the whole person.

2.2 **Foster an interconnected health ecosystem:** Create novel capabilities to advance the integration of health-related systems, from the individual to population scale. These innovations will streamline coordination across clinical care, operations, public health, research, and community health. Efforts in this area will strengthen the connectivity, interoperability, and operational efficiency of health infrastructure to facilitate safe, secure, and seamless exchange of information among health care providers, patients, researchers, and stakeholders.

2.3 **Enhance stability, adaptability, and robustness across the health ecosystem:** Innovate agile and sustainable approaches to anticipate, mitigate, and adapt to evolving health challenges. Efforts will explore new paradigms to minimize disruptions caused by supply chain shortages, emerging pathogens, or catastrophic events. Such approaches will leverage artificial intelligence (AI), decentralized models, predictive analytics, and adaptive technologies to broaden the availability of high-quality care, reduce pressure and vulnerabilities on the health ecosystem, and enhance emergency response.

Goal 3: Drive Scalable Solutions to Improve Health Care Access and Affordability

ARPA-H will leverage an interdisciplinary approach and collaborative networks to create programs that address challenges of geography, distribution, manufacturing, data and information, thereby improving health care access and affordability. In the United States, many communities and remote areas lack access to timely and quality health care, which leads to disparities in health outcomes for those populations. Bottlenecks during the manufacturing processes of products and health technologies also lead to delays and limited availability, preventing effective distribution of health care solutions to areas of need, especially in emergencies.

ARPA-H will improve the scalability and affordability of health care solutions, bridge gaps in underserved areas, and extend remote access to expertise by developing location-specific interventions, telemedicine solutions, and mobile health clinics. Through its focus on rapid innovation and local partnerships, as well as flexible distribution networks and streamlined manufacturing processes, ARPA-H will accelerate the availability of critical health care technologies and makes them more affordable for everyone.

Goal 3 Objectives

3.1 **Enhance affordability through scalable technologies and interventions:** Prioritize research and development efforts aimed at creating scalable health care technologies and interventions that reduce cost. These efforts include investing in innovative approaches to improve affordability, such as drug-repurposing, telemedicine, point-of-care diagnostics, and modular health care infrastructure, that can be rapidly deployed and adapted to various geographic, economic, and manufacturing contexts.

3.2 **Establish collaborative distribution networks:** Partner with local communities, health care providers, and technology companies to establish collaborative distribution networks that address challenges related to geography, affordability, manufacturing, and economies of scale, ensuring equitable, quick, and efficient “last mile” delivery of health care solutions.

3.3 **Lead the biomanufacturing revolution:** Drive innovation at the intersection of biology and technology to redefine the landscape of biomanufacturing, empowering scientists and industries to rapidly translate cutting-edge research into life-changing products, secure the health supply chain, and accelerate the pace of scientific discovery.

Goal 4: Build Proactive Health Capacity to Keep People from Becoming Patients

ARPA-H will raise public awareness, foster a culture of proactive health management, and implement innovative strategies that empower individuals to take charge of their wellness to mitigate the development of health issues. Currently, health care systems focus almost exclusively on treating illnesses and managing existing conditions, so advances are needed to generalize from a sick care system to a well care system that keeps people healthy for longer. Disparate factors affect health outcomes, including health care access, education, economic resources, community support services, and living environments. Efforts to keep individuals from becoming patients are currently hindered by limited public awareness about preventive health practices, inadequate incentives for health care providers, and a lack of comprehensive, personalized approaches to assess risk early. There is a critical need for a paradigm shift from a reactive model centered on treating illnesses to a proactive one that prioritizes preventive measures and furthers holistic health promotion strategies.

ARPA-H will invest in new preventative programs that can detect and characterize disease risk, promote treatments and behaviors that anticipate threats to American's health — whether those threats are viral, bacterial, chemical, physical, or psychological — and help bridge the gap in health disparities.

Goal 4 Objectives

4.1 **Promote prevention and wellness:** Lead initiatives to enhance public awareness and education on preventive health practices. By leveraging innovative communication channels, digital platforms, and community engagement, ARPA-H aims to disseminate accurate and accessible information about healthy lifestyles, risk factors, and early detection, thereby empowering individuals to make informed decisions about their health and reducing the likelihood of preventable health issues.

4.2 **Foster interdisciplinary collaboration for holistic health:** Facilitate collaboration among health care providers, researchers, technologists, and community stakeholders to develop comprehensive and personalized approaches to proactive health management. By integrating data-driven insights, genomic insights, wearable technologies, and behavioral science, ARPA-H aims to create a holistic framework for early risk assessment and tailored interventions.

4.3 **Incentivize health care transformation toward prevention:** Reshape U.S. health care incentives to prioritize preventive measures and proactive health practices. By partnering with policymakers, payers, and health care institutions, ARPA-H aims to develop innovative reimbursement models, financial incentives, and regulatory frameworks that reward health care providers for promoting and practicing preventive care.

Goal 5: Foster Data-Driven Innovation Across the Health Ecosystem

ARPA-H will establish and maintain a data ecosystem to accelerate and leverage health care and life science research for real world impact, expedite ARPA-H program formulation, and track how ARPA-H investments affect long term health outcomes. Presently, researchers invest substantial time in procuring, cleansing, and preparing data. Additionally, the exponential growth of medical data, from electronic health records (EHR) to wearable devices, compounded with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and other privacy requirements, poses challenges in managing and extracting meaningful insights from available data. The complex interplay of factors influencing health outcomes, including genetics, lifestyle, and environmental factors, necessitates a holistic approach that only advanced data analytics can provide.

ARPA-H aims to develop data-driven architecture that will leverage integrated data and sophisticated analytical tools, including the transformative potential of machine learning (ML) and recent advancements in generative AI, to seamlessly acquire data from diverse sources like ARPA-H programs, EHR, diagnostic records, images, Internet of Things (IoT) data, genetics and other omics data, and health care and life science research data from labs. ARPA-H aims to provide tools to identify data quality issues, perform automatic remediation, and facilitate data sharing while ensuring security and privacy. These capabilities, if successful, will generate new avenues of exploration in diagnostics, therapeutics, personalized medicine, disease modeling, and data analytics, ultimately leading to improved health outcomes and a more efficient and responsive health care system.

ARPA-H recognizes that disadvantaged communities are often under-represented in research, which will be exacerbated if artificial intelligence models are trained only on readily available data. ARPA-H will seek to develop data technologies that encourage underrepresented groups to participate in research, including technologies that build trust in data and enable visibility into how participation in research benefits their specific communities. Within the organization, ARPA-H will enable a data-driven culture where IT infrastructure, applications, data management, cybersecurity, and IT governance foster collaboration with partners, drive effective decision-making, inform resource allocation, and enable comprehensive strategies to strengthen ARPA-H's security posture, safeguard research assets, and ensure compliance with data privacy standards.

Goal 5 Objectives

5.1 **Establish collaborative data sharing capabilities:** Develop and implement standardized data sharing protocols and platforms to eliminate data silos, foster collaboration, and ensure that relevant and comprehensive data is accessible for research, analysis, and innovation across the entire health ecosystem, including with international partners.

5.2 **Identify opportunities to expand representation of underrepresented groups in research data:** Drive empowered participation in research and data sharing by groups traditionally underrepresented in research to increase availability of data representing the diversity of the American people – and, thus, more representative health solutions.

5.3 **Harness generative AI for resource-optimized health technology R&D:** Leverage the capabilities of generative AI to develop a sophisticated decision support system. This system will inform allocation of resources, prioritization of research initiatives, and decisions about investment choices within health technology R&D to ensure alignment with the most promising opportunities.

Goal 6: Increase the Probability of Successful Transition

ARPA-H-funded biomedical and health research breakthroughs and innovation will only be successful if they get to the American people. In practice this means transitioning programs and capabilities out of the agency and into the policies, products, and services that reach all Americans.

ARPA-H will coordinate efforts to minimize duplication and facilitate new coalitions to successfully transition high-risk/high-reward initiatives, programs, and capabilities for downstream adoption. Through growing ARPA-H's nationwide network and presence across all 50 states, supporting PM and performer engagement with potential partners and funders, providing guidance on business and regulatory processes, and offering many other transition-focused services, ARPA-H will demonstrate the pathways to successful translation at each stage of the research program lifecycle. In doing so, the agency will de-risk its investments and ensure that research products can be sustained without additional ARPA-H funding.

Goal 6 Objectives

6.1 **Establish and build a health innovation network to ensure ARPA-H capabilities reach all Americans:** ARPA-H will continue to operate under a hub and spoke model to form a network of people, institutions, and capabilities placed within relevant geographies and with diverse populations across the spectrum of health-related social needs and support systems that impact health outcomes. With the stakeholder engagement hub dedicated to developing partnerships, the customer experience hub featuring human-centered approaches to product and service design, and the investor catalyst hub helping to bring ideas to market, ARPA-H continues to be engaged across the entire United States.

6.2 **Connect stakeholder insights and partnerships:** ARPA-H will continue to develop partnerships across federal and community networks to connect Program Managers to investors, entrepreneurs, partners, customers, technical experts, and other Federal agencies throughout the program lifecycle. These connections ensure that efforts are not redundant and increase performers' abilities to significantly advance the state of the art.

6.3 **Support performer teams to bring the most compelling solutions to bear:** ARPA-H is invested in the long-term success of performers and provides services such as resources to bridge gaps between prototypes and products, business and entrepreneurship coaching education, and regulatory support to accelerate performer progress.

Goal 7: Build a World-Class Organization

ARPA-H is committed to building and maintaining alignment of its people, resources, strategy, governance, and technology. Through an adaptive human capital strategy, strong stewardship of resources, effective planning practices, and an information technology strategy rooted in technological innovation, ARPA-H will support the development of high-impact solutions to the nation's most challenging health problems.

Goal 7 Objectives

7.1 **Recruit, retain, and develop leading talent across the ARPA-H enterprise:** ARPA-H will sustain a workforce of talented operational staff and program managers that demonstrate diversity of lived experience, geography, and scientific, technical, and management expertise from government, industry, academia, and think tanks, among others. Through building a bold, expert workforce, cultivating an administratively and scientifically nimble culture, and providing modernized, flexible workspace, ARPA-H will ensure that federal employees and contractors represent broad populations across the biomedical and health landscape and possess the skills, competencies, and tools required to achieve the agency's mission.

7.2 **Maintain strong stewardship of financial resources:** ARPA-H is committed to effective financial stewardship and risk management to ensure prudent use of resources. Through robust financial management practices, ARPA-H will focus on transparency and accountability to maintain program integrity, effective internal controls, and public trust.

7.3 **Promote effective strategy, planning, and execution practices:** ARPA-H is invested in agile and iterative strategy and planning to prioritize efforts, monitor progress, and facilitate agency responsiveness to emerging opportunities and threats, as well as promoting effective governance, data- and evidence-driven processes, and a culture of accountability that enables strategic decision-making across the agency.

Anticipated Outcomes

Through implementation of this strategy, ARPA-H anticipates generating demonstrable outcomes across all goals and maintaining responsiveness to emerging opportunities. The initial portfolio of programs and projects aims to yield the following outcomes by the end of FY26:

- Developed novel technologies and therapeutic modalities to produce non-invasive methods for bone and cartilage regeneration.
- Established partnerships with federal agencies and engaged patient and advocate communities to develop novel technologies that increase surgical precision and accuracy, thereby improving cancer patient outcomes in hospitals.
- Developed technologies to better understand the dysregulation of cellular processes common in the formation of cancer.
- Advanced clinical trial readiness to recruit 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.
- Enhanced the current state of gene-encoded technology by developing platform capabilities, such as RNA-encoded immune system modulation to enhance protective immune responses.
- Developed and validated a set of scalable and disease-agnostic methods that could be targeted to any tissue, transforming the treatment of cancer, neurological conditions, and complex diseases such as autoimmune conditions.
- Advanced capabilities to address long-standing challenges in antimicrobial resistance, including developing devices that generate an antibiotic susceptibility profile for infections before the patient leaves the clinic to end misprescription of antibiotics.
- Developed capabilities to improve the accuracy and cost effectiveness of air quality biosensors.

- Driven fundamental advances in safety, trustworthiness, and accuracy of artificial intelligence techniques 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 health care ecosystem.
- Introduced new economic incentives, through development of scalable and outcome-oriented tools and processes, to encourage better preventive health care and improve outcomes related to heart attacks and strokes, pregnancy complications, and harms related to alcohol abuse and opioid overdoses, in defined geographic populations.
- Provided new tools to improve digital health security, software assurance, and software usability technologies to address weaknesses in current U.S. health care infrastructure, increase system resiliency, and improve the quality of care rendered to patients.
- Established capabilities to address technical challenges that make it difficult to combine data by advancing high-fidelity data collection, integration of electronic health records, semantic mapping, large language model query mechanisms, and multi-source data exploration.
- Begun to build trust with underrepresented communities through innovative mechanisms for privacy-preserving data sharing.
- Contributed to ensuring the United States maintains global leadership in biomedical and health science, technology, and innovation through its programs and other initiatives, as well as coordination and collaboration with international partners.

Conclusion

This document outlines ARPA-H's Strategic Plan for the fiscal years 2024 to 2026. As required by the Consolidated Appropriations Act of 2023, every three years a new Strategic Plan will be formulated and transmitted to the Senate Committee on Health, Education, Labor, and Pensions, the Senate Committee on Appropriations, the House of Representatives Committee on Energy and Commerce, and the House of Representatives Committee on Appropriations.

ARPA H