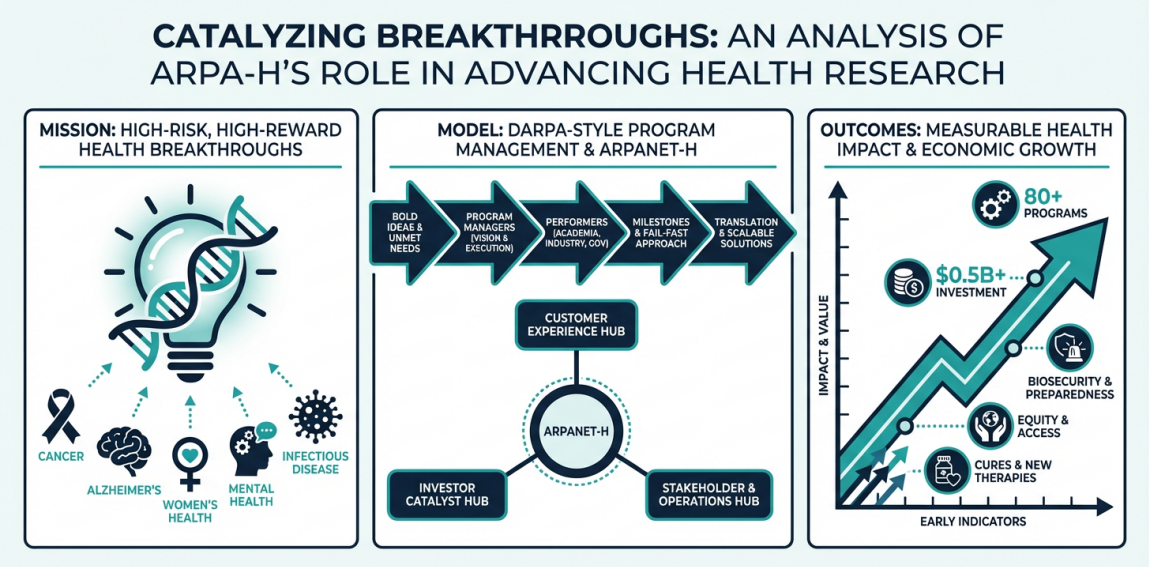

Catalyzing Breakthroughs

An Analytical Policy Report on the Role of the
Advanced Research Projects Agency for Health (ARPA-H)
in Advancing U.S. Health Research and Science

Prepared for policymakers, congressional staff, public-health leaders, and academic-industry partners

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April 2026

This report synthesizes publicly available statutes, congressional appropriations, ARPA-H press releases, GAO oversight reports, peer-reviewed analyses, and comparative agency studies as of April 2026.

Abstract

The Advanced Research Projects Agency for Health (ARPA-H) was established in March 2022 and given permanent statutory authority in December 2022 (42 U.S.C. § 290c) as the United States' first health-focused agency built on the "ARPA model" pioneered by the Defense Advanced Research Projects Agency (DARPA) sixty-four years earlier. Endowed with annual appropriations of $1.0–1.5 billion, empowered Other Transaction Authority (OTA), a national hub-and-spoke innovation network (ARPANET-H), and a portfolio of more than eighty mission-driven programs, ARPA-H has been positioned as a structural intervention in the chronic "valley of death" that separates basic biomedical discovery from delivered patient benefit. This 40-page policy report assesses, in balanced fashion, whether ARPA-H is fulfilling that role. We document its founding rationale, organizational design, program portfolio, and early impact; benchmark its operating model against DARPA, ARPA-E, the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), and analogous foreign agencies (UK ARIA, Germany SPRIN-D); analyze critiques from the U.S. Government Accountability Office, peer-reviewed commentaries, and the academic biomedical community; and evaluate the agency's vulnerability following the February 2025 dismissal of inaugural director Dr. Renee Wegrzyn. We conclude that ARPA-H represents a *plausible but unproven* addition to the U.S. biomedical innovation ecosystem: its structural advantages—empowered program managers, milestone-driven contracting, affordability mandates, and a national network—are real and substantively differentiate it from NIH and BARDA, but the agency must navigate political volatility, immature workforce planning, and the long maturation horizon of biomedical breakthroughs (10–15 years) before its impact can be definitively measured. We close with seven evidence-based policy recommendations to strengthen ARPA-H's institutional resilience, evaluation framework, and translational reach.

Top-line conclusions:

1. ARPA-H meaningfully advances U.S. health research *by design*, but realized impact at scale will not be measurable for another 7–12 years given biomedical translation timelines.
2. The agency's chief structural innovation—DARPA-style empowered program managers paired with affordability/access mandates—is plausibly the most consequential procurement reform in U.S. biomedical R&D since the Bayh-Dole Act (1980).
3. Severe political risk emerged in February 2025 with the firing of Dr. Wegrzyn; institutional resilience now depends on Congressional protection, transparent metrics, and avoiding mission drift.
4. ARPA-H's $\sim$ $1.5 billion budget is small ($\sim$3% of NIH), so its leverage depends on *focus*, not scale; broadening its mission would likely undermine effectiveness.

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1. Executive Summary for Policymakers

The United States spends more on biomedical research than any other nation—$245 billion in 2023 across federal, industry, and philanthropic sources, of which $47.1 billion flows through the National Institutes of Health (NIH) and another $1.5 billion through the new Advanced Research Projects Agency for Health (ARPA-H) [21–23]. Yet only about 14% of new drugs that enter Phase I trials achieve approval, average development costs exceed $2.6 billion per approved compound (capitalized), and patients in the United States routinely wait a median of 12–15 years to access therapies whose mechanisms were established in academic laboratories [1–3]. This persistent "valley of death" between scientific promise and clinical impact is not principally a problem of insufficient discovery; it is a problem of *translation*, *coordination*, and *scaled investment in late-stage applied research*.

ARPA-H was established explicitly to address that gap. Announced by President Biden in April 2021, stood up administratively within the Department of Health and Human Services (HHS) on March 15, 2022, codified by Public Law 117-328 in December 2022, and given an inaugural director (Dr. Renee Wegrzyn) on October 11, 2022, the agency now operates four mission offices, a national hub-and-spoke network (ARPANET-H) anchored in Dallas, Cambridge, and Washington, D.C., and more than eighty discrete programs whose budgets range from $3 million "sprint" awards (e.g., the Sprint for Women's Health) to $144 million multi-year platform investments (e.g., PROSPR) [6, 17, 22, 25, 28].

Why this matters. If ARPA-H succeeds, it will deliver measurable, decade-defining health gains: earlier cancer detection at population scale, objective measures of mental health, equitable diagnostics for rural and underserved Americans, biomanufacturing resilience against pandemic threats, and platform technologies (mRNA, AI/ML, gene editing, regenerative medicine) that compound benefits across diseases. If it fails—through political defunding, mission drift, or capture by traditional funding constituencies—the United States will have squandered a once-a-generation opportunity to professionalize the translation of biomedical breakthroughs and will likely cede biotechnology leadership to peer competitors that are now standing up analogous agencies (UK ARIA, Germany SPRIN-D, Japan AMED-A).

What this report does. Section 2 provides historical and contextual background. Section 3 dissects ARPA-H's organizational design, statutory authorities, and ARPANET-H. Section 4 catalogs the program portfolio and notable awards through April 2026. Section 5 benchmarks the ARPA-H operating model against DARPA, NIH, BARDA, ARPA-E, ARIA, and SPRIN-D. Section 6 evaluates early impact and indicators. Section 7 presents critiques and risks, including the December 2024 GAO report and the February 2025 leadership upheaval. Section 8 integrates a SWOT analysis. Section 9 delivers seven specific, evidence-based recommendations for Congress, the Secretary of HHS, the next ARPA-H Director, and the broader biomedical research community.

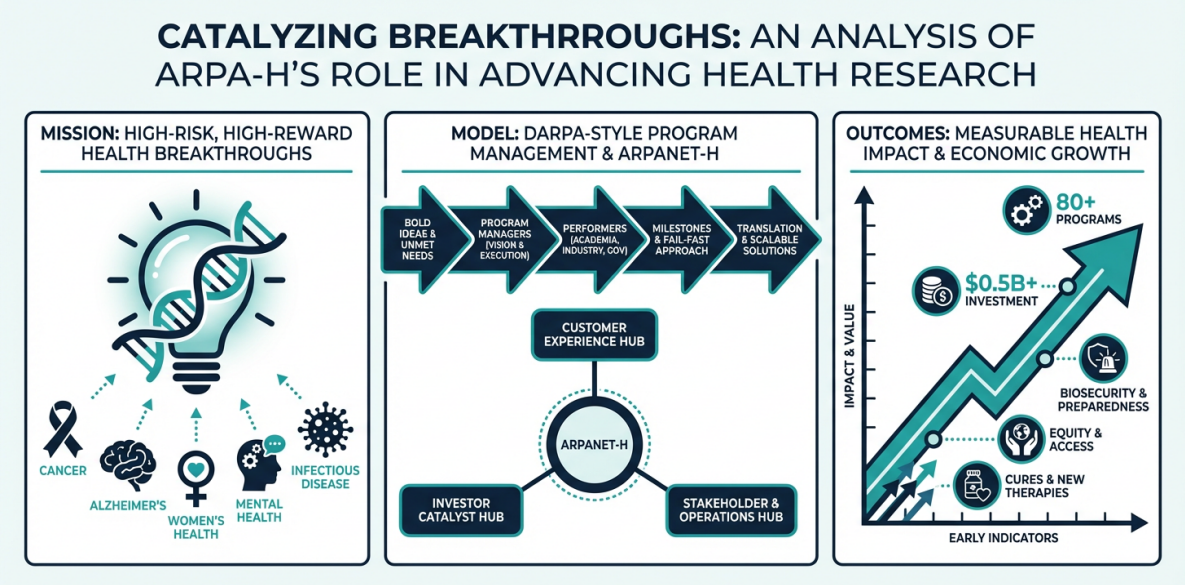


Figure 1: Graphical abstract: *Mission*, *Model*, and *Outcomes* of ARPA-H. The agency's mission spans women's health, cancer, Alzheimer's, mental health, and infectious disease; its model centers on empowered program managers, milestone-based Other Transaction Agreements, and a hub-and-spoke national network; its outcomes are measured in cures delivered, equity in access, biosecurity, and platform technologies. This report assesses each panel in detail.

2. Background and Context: Why an ARPA-H?

2.1. The chronic translation gap in U.S. biomedical research

The United States has built, over seventy-five years, the world's most productive basic biomedical research enterprise. NIH alone funds nearly 60,000 grants per year supporting more than 300,000 researchers at 2,500 universities, medical schools, and other institutions [21]. Galkina Cleary and colleagues, analyzing 210 new molecular entities approved by the FDA between 2010 and 2016, demonstrated that *every single one* drew on NIH-funded research: $115 billion of NIH funding (in inflation-adjusted dollars) underpinned the basic discoveries enabling those approvals, with each drug receiving an average of $839 million in foundational federal research investment [1]. The American basic-research engine works.

What does *not* work as reliably is the conversion of those discoveries into approved, accessible products. DiMasi, Grabowski, and Hansen estimate the capitalized cost of bringing a single new molecular entity to market at approximately $2.6 billion (2013 dollars) over an average development time of 13.5 years, with the dominant cost driver being failure: only 14% of compounds entering Phase I clinical trials ultimately gain approval [2]. Wong, Siah, and Lo, analyzing 21,143 unique compound-indication pairs, refined this estimate—finding that overall probability of clinical success is 13.8%, with oncology trials succeeding at only 3.4%—and emphasized the disproportionate failure rate in the late translational stages [3].

The structural problem is that NIH's investigator-initiated grant system is optimized for hypothesis-driven discovery, not for goal-driven translation; industry's profit-driven incentives systematically underinvest in technologies with diffuse public benefit (vaccines, antibiotics, diagnostics

for rare diseases, mental-health interventions) or in foundational platforms whose returns accrue across many products; and BARDA, while extraordinarily effective in countermeasure development, is statutorily focused on national-security pathogens. The space between basic discovery and end-stage clinical development—roughly Technology Readiness Levels (TRL) 3 through 7—has historically been chronically under-resourced. Figure 2 depicts this "valley of death" visually.

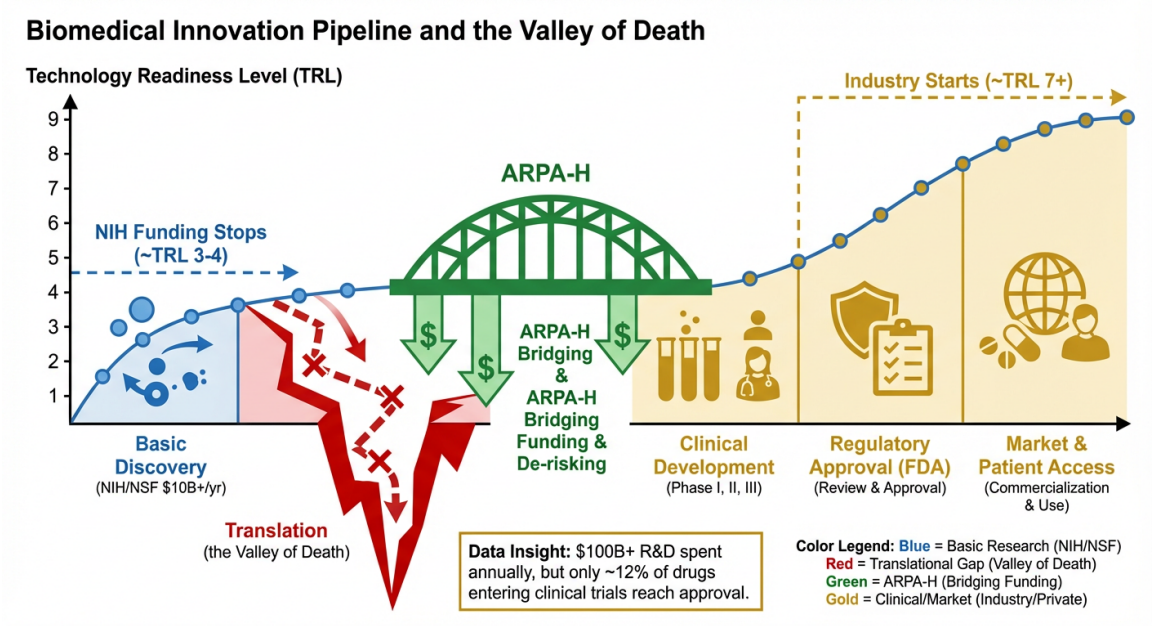


Figure 2: The "valley of death" in U.S. biomedical innovation. NIH and NSF disproportionately fund TRL 1–3 (basic discovery); industry concentrates capital at TRL 7+ (late clinical development and commercialization). The intermediate translational stages—where most attrition occurs—have historically been underfunded by both sectors. ARPA-H is positioned explicitly to bridge this canyon through milestone-driven, time-bounded, mission-oriented investments. Sources: [1–3].

2.2. The DARPA precedent

The institutional template that ARPA-H most directly emulates is the Defense Advanced Research Projects Agency (DARPA), founded in February 1958 in response to the Soviet launch of Sputnik [16, 33]. DARPA's sixty-six-year track record is unusually concrete: ARPANET (the technical foundation of the Internet); the Global Positioning System; stealth aircraft; modern unmanned aerial systems and self-driving vehicles; foundational investments in messenger-RNA delivery technologies that enabled rapid COVID-19 vaccine development at Moderna and Pfizer-BioNTech; and seminal advances in artificial intelligence dating to the 1960s [33, 34]. Bonvillian and colleagues, in the most authoritative book-length treatment, identify five organizational features that define what they term the "ARPA model" [16]:

1. **Empowered program managers** (typically term-limited 4–6 years) who define a problem, recruit performers, and have authority to start and stop projects.

2. **Mission-driven, time-bounded portfolios** structured around concrete capability targets rather than open-ended scientific inquiry.

3. **Other Transaction Authority (OTA)**, a flexible non-FAR contracting instrument that permits

milestone-based payments, terminations, and customized intellectual-property arrangements.

4. **Tolerance for high-risk failure**, accompanied by rigorous Heilmeier-Catechism-based selection ("What are you trying to do? How is it done today? What's new about your approach? Who cares? If you succeed, what difference will it make?").

5. **Lean, flat organizational structure**, deliberately small (DARPA's headcount is ∼220 staff against an annual budget of $4.0 billion in FY2024).

Azoulay, Fuchs, Goldstein, and Kearney have shown empirically that this model is associated with higher rates of patenting and start-up creation per federal dollar than traditional grant-making [35]. The model has been extended to Intelligence (IARPA, 2006), Energy (ARPA-E, 2009), Homeland Security (HSARPA, 2002), and now Health (ARPA-H, 2022).

2.3. Why now?

Three converging conditions made the establishment of ARPA-H politically feasible in 2021–2022. First, the COVID-19 pandemic demonstrated both the United States' biomedical capacity (mRNA vaccines reached emergency use authorization within 326 days of the SARS-CoV-2 genome publication) and its limitations (testing capacity, supply-chain resilience, biosurveillance). Second, the Cancer Moonshot, relaunched by President Biden in February 2022 with a goal of halving the cancer death rate within 25 years, created political momentum for ambitious, mission-driven biomedical investment. Third, a coalition of biomedical thought leaders—Eric Lander (then Director of OSTP), Francis Collins (then NIH Director), Lawrence Tabak, Tara Schwetz, and external advocates including the Federation of American Scientists Day One Project—made an empirically grounded case that translational biomedicine needed an institution structurally distinct from NIH [36–38].

2.4. Statutory establishment and budget history

President Biden's FY2022 budget request originally proposed $6.5 billion over three years for ARPA-H [38]. Congress, while supportive of the concept, scaled the appropriation considerably and folded it within a one-year accounting framework. The agency's appropriations and authorities are summarized in Table 1 and visualized in Figure 3.

Table 1: ARPA-H statutory and budget history, FY2022–FY2026.

Date / Fiscal Year	Event / Status	Appropriation
Apr 2021	President Biden announces ARPA-H concept (FY22 budget request: $6.5B over 3 years)	—
Mar 15, 2022	HHS Secretary Becerra establishes ARPA-H administratively within NIH	—
FY 2022	Initial appropriation through Consolidated Appropriations Act, 2022	$1.0B
Oct 11, 2022	Dr. Renee Wegrzyn appointed as inaugural Director	—
Dec 29, 2022	PL 117-328 codifies ARPA-H at 42 U.S.C. § 290c (independent within HHS)	—
FY 2023	Consolidated Appropriations Act, 2023	$1.5B
FY 2024	Further Consolidated Appropriations Act, 2024	$1.5B
FY 2025	Continuing resolution; enacted appropriation	$1.5B
FY 2026	Continuing resolution; enacted appropriation	$1.5B
Feb 2025	Trump administration dismisses Director Wegrzyn	—

Sources: [4, 22, 23, 29, 30, 39].

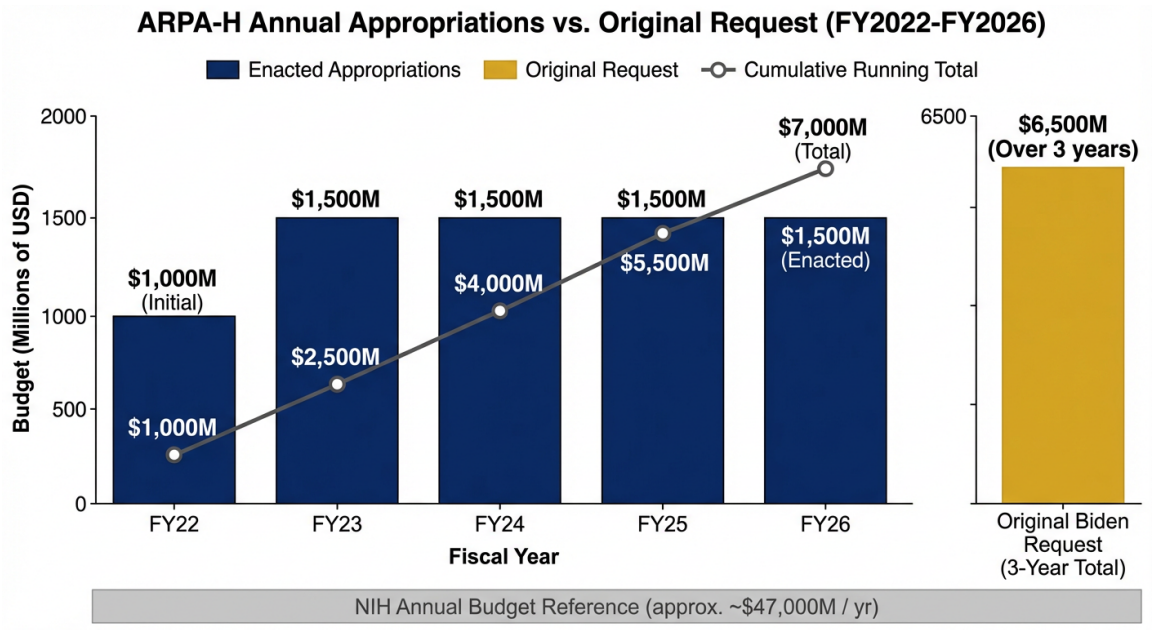


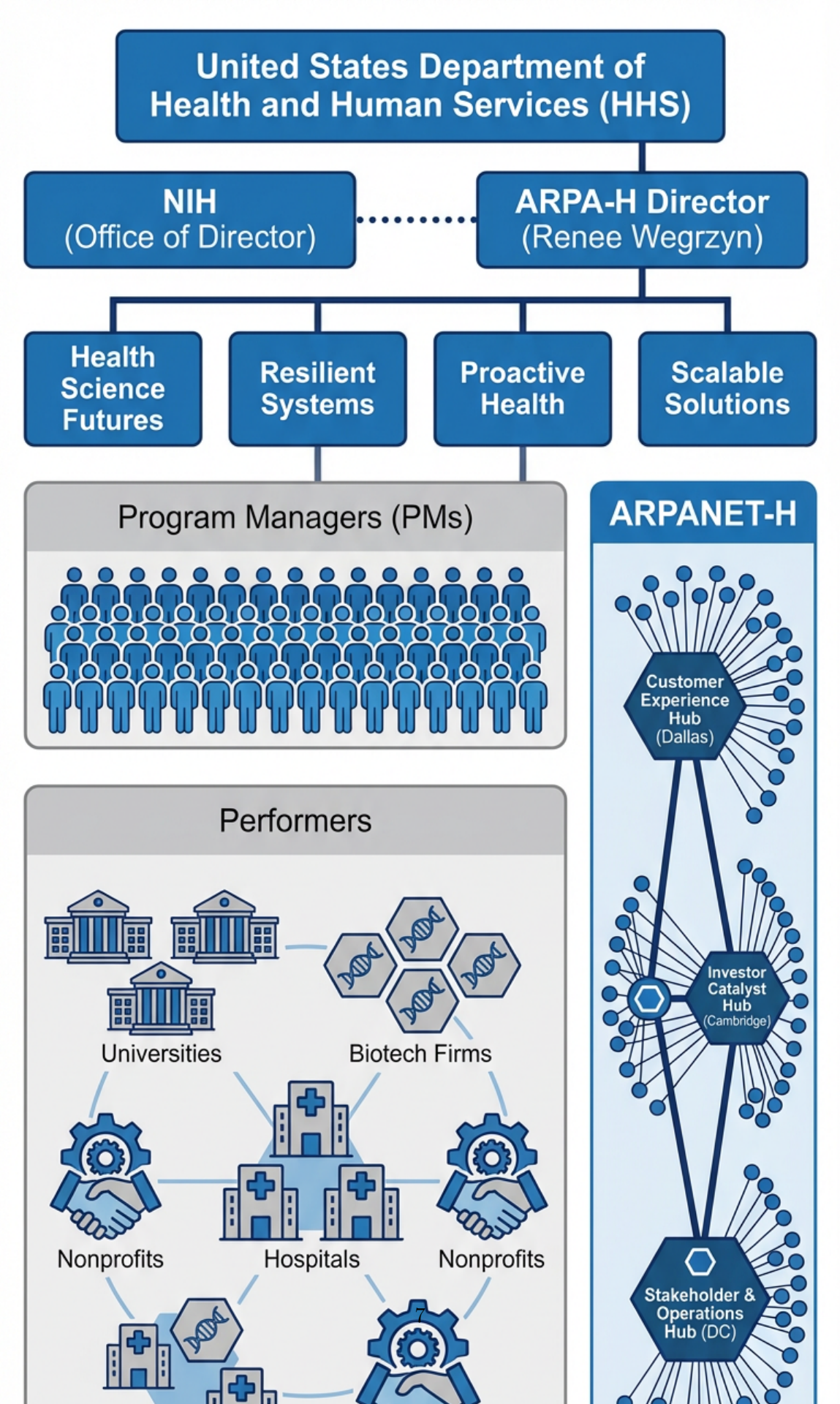
Figure 3: ARPA-H annual appropriations FY2022–FY2026 versus the Biden administration's original $6.5 billion three-year request. Cumulative funding through FY2026 totals $7.0 billion. For reference, NIH's FY2024 enacted budget was $47.1 billion—approximately 31× ARPA-H. ARPA-H's leverage is therefore not a function of scale, but of *focus* and *contracting flexibility*.

3. Organizational Structure and Statutory Authority

3.1. Statutory location: independent within HHS, administratively linked to NIH

A core debate during ARPA-H's establishment was whether the new agency should sit *within* NIH or *independently* of NIH within HHS. NIH leadership (Collins, Tabak, Schwetz) initially favored embedding ARPA-H inside NIH to leverage scientific staff, peer-review infrastructure, and institutional knowledge [40]. A countervailing coalition—including Eric Lander, the Federation of American Scientists, and many academic critics—argued that an embedded agency would inevitably be subjected to NIH's investigator-initiated culture, peer-review timelines, and academic review committees, defeating the very purpose of an ARPA-style organization [37, 41].

The Consolidated Appropriations Act, 2023 (PL 117-328) ultimately resolved the question by codifying ARPA-H at 42 U.S.C. § 290c as an entity *within HHS* but *outside NIH*, while administratively maintaining its location at the NIH Office of the Director and on the NIH Bethesda campus for at least the agency's first 30 months [4, 42]. The director reports directly to the Secretary of HHS, not to the NIH Director, and the agency's appropriation is a separate line item. Figure 4 depicts the full organizational chart.


United States Department of Health and Human Services (HHS)
NIH (Office of Director)
ARPA-H Director (Renee Wegrzyn)
Health Science Futures
Resilient Systems
Proactive Health
Scalable Solutions
Program Managers (PMs)
ARPANET-H
Customer Experience Hub (Dallas)
Investor Catalyst Hub (Cambridge)
Stakeholder & Operations Hub (DC)
Performers
Universities
Biotech Firms
Nonprofits
Hospitals
Nonprofits

3.2. Leadership team and the program-manager corps

Inaugural director. Dr. Renee Wegrzyn, a synthetic biologist with a Ph.D. from the Georgia Institute of Technology, served as ARPA-H's inaugural director from October 11, 2022, until her dismissal on February 14, 2025 [29, 30, 43, 44]. Wegrzyn was a notably strong selection: she had previously served as a DARPA program manager (2016–2020), where she ran the Safe Genes program on gene-editing safety, and as Vice President of Business Development at Ginkgo Bioworks, where she led the company's Concentric biosecurity initiative. Her dual experience inside DARPA's ARPA-model culture and inside a publicly traded biotechnology company gave her unusual fluency in both the federal-procurement and commercial-translation aspects of the agency's mandate.

Deputy director. Dr. Susan Monarez, a public-health and biosecurity expert with prior service at the White House Office of Science and Technology Policy (OSTP), the National Security Council (NSC), the Department of Homeland Security's HSARPA, and BARDA, was appointed deputy director in 2023 [45, 46].

Program managers. ARPA-H's ∼30 program managers, recruited primarily from industry (biotech, medical-device companies, AI firms) and from senior academic ranks, are appointed under terms typically limited to 3–5 years and are explicitly modeled on DARPA's program-manager corps. The Heilmeier Catechism is the agency's working framework for program design [16].

3.3. The four mission offices

ARPA-H organizes its programs through four thematic "mission offices" [5, 7]:

1. **Health Science Futures.** Foundational platform technologies: gene editing, AI for biology, biomanufacturing, advanced therapeutics. Programs include CUREIT (mRNA-based immune training) and BDF Toolbox.

2. **Resilient Systems.** Pandemic preparedness, antimicrobial resistance, supply-chain robustness, biosecurity. Programs include ADAPT and biothreat detection.

3. **Proactive Health.** Prevention, early detection, behavioral health, women's health, healthy aging. Programs include the Sprint for Women's Health, EVIDENT (behavioral health), and the Healthy Aging investments.

4. **Scalable Solutions.** Equity, rural health, manufacturing scale, deployment of digital health. Programs include REACH and INDEX.

Figure 5 summarizes the four offices, their programs, and cross-cutting capabilities.

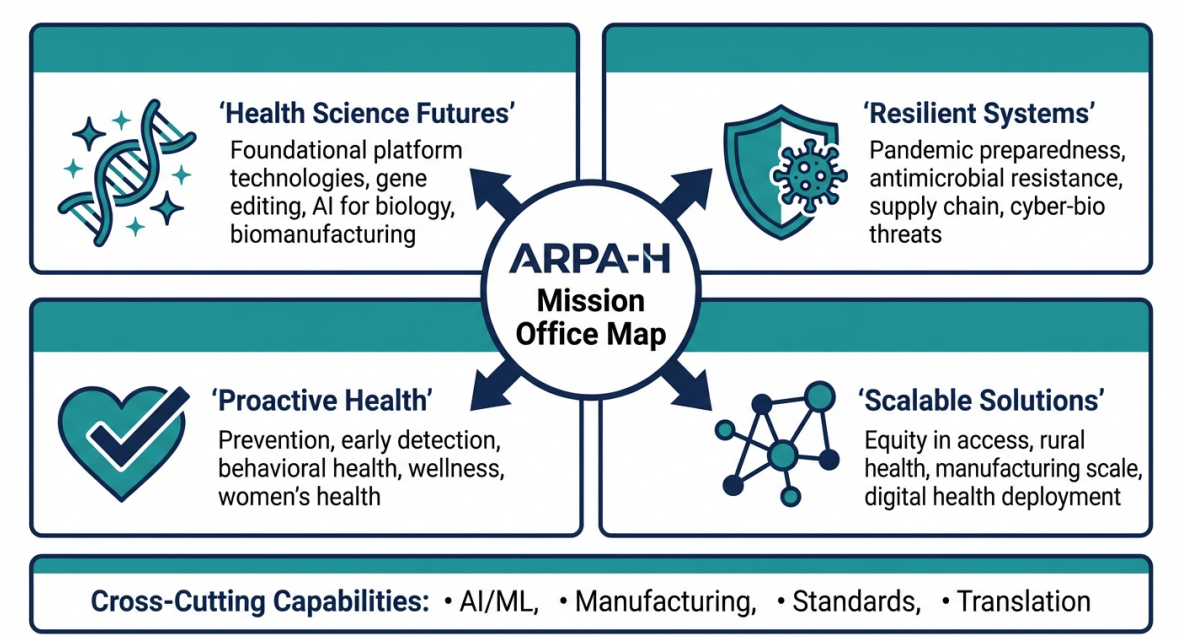


Figure 5: ARPA-H's four mission offices and representative programs. Cross-cutting capabilities (AI/ML, manufacturing, standards, translation services) are shared across all four offices and supported by the ARPANET-H network. Sources: [5, 7–11].

3.4. ARPANET-H: the hub-and-spoke health innovation network

A structural innovation distinguishing ARPA-H from DARPA is the ARPANET-H national health innovation network, launched in May 2023 [6, 12]. The network consists of three regional "hubs," each with distinct functions, and a dynamic, growing network of "spokes" nationwide:

- **Customer Experience Hub** (Dallas, Texas; led by Advanced Technology International / VentureWell consortium): convenes patients, clinicians, and community organizations to ground programs in real-world clinical workflows.
- **Investor Catalyst Hub** (Cambridge, Massachusetts; led by VentureWell consortium): facilitates private-capital follow-on investment, supports start-up formation, and accelerates commercial transition.
- **Stakeholder and Operations Hub** (Washington, D.C.; led by The MITRE Corporation): handles federal, regulatory, and inter-agency coordination, including alignment with the FDA, CDC, and CMS.

Spokes include hospital systems (Mayo Clinic, Texas Medical Center, MD Anderson, Johns Hopkins), academic institutions (the University of Montana Health Research Partnership being a confirmed example), start-ups, patient-advocacy groups, venture-capital firms, and community health centers [12, 13]. As of April 2026, ARPA-H has not published a complete spoke roster, though public reporting suggests dozens of spokes are active. Figure 6 provides a schematic geographic map of the network.

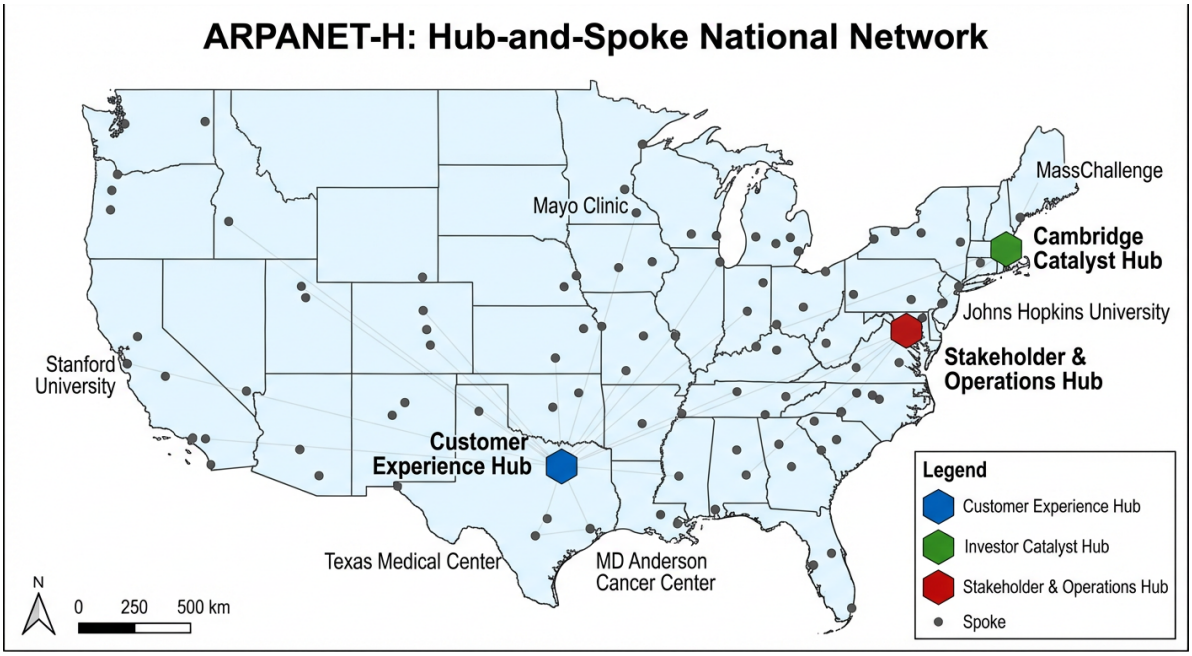


Figure 6: The ARPANET-H national hub-and-spoke health innovation network. Three regional hubs in Dallas (Customer Experience), Cambridge (Investor Catalyst), and Washington, D.C. (Stakeholder & Operations) coordinate a dynamic network of spokes that includes hospital systems, academic institutions, biotech start-ups, venture-capital firms, patient-advocacy groups, and community health centers. The network is intentionally distributed to serve geographies under-represented in traditional NIH-funded research. Sources: [6, 12, 13].

3.5. Other Transaction Authority and the contracting toolkit

A defining capability of ARPA-H, inherited from DARPA, is Other Transaction Authority (OTA). Unlike traditional Federal Acquisition Regulation (FAR)-based contracts and grant-based awards (which dominate NIH), OTAs are flexible, milestone-driven, non-FAR agreements that allow [14, 15, 47]:

- Award timelines as short as 30–60 days from selection to obligation.
- Termination of underperforming projects at pre-specified milestones.
- Tailored intellectual-property arrangements (often more favorable to performers than Bayh-Dole defaults).
- Cost-share, in-kind contributions, and co-investment with private capital.
- Inclusion of non-traditional performers (start-ups, nonprofits, individual inventors) that may struggle with FAR compliance.

ARPA-H's January 2026 OT Training document explicitly aligns its OT practice with DARPA's, including the use of milestone-based "Phase I/II/III" construction, where each phase has go/no-go criteria [14]. Figure 7 shows the typical program lifecycle.

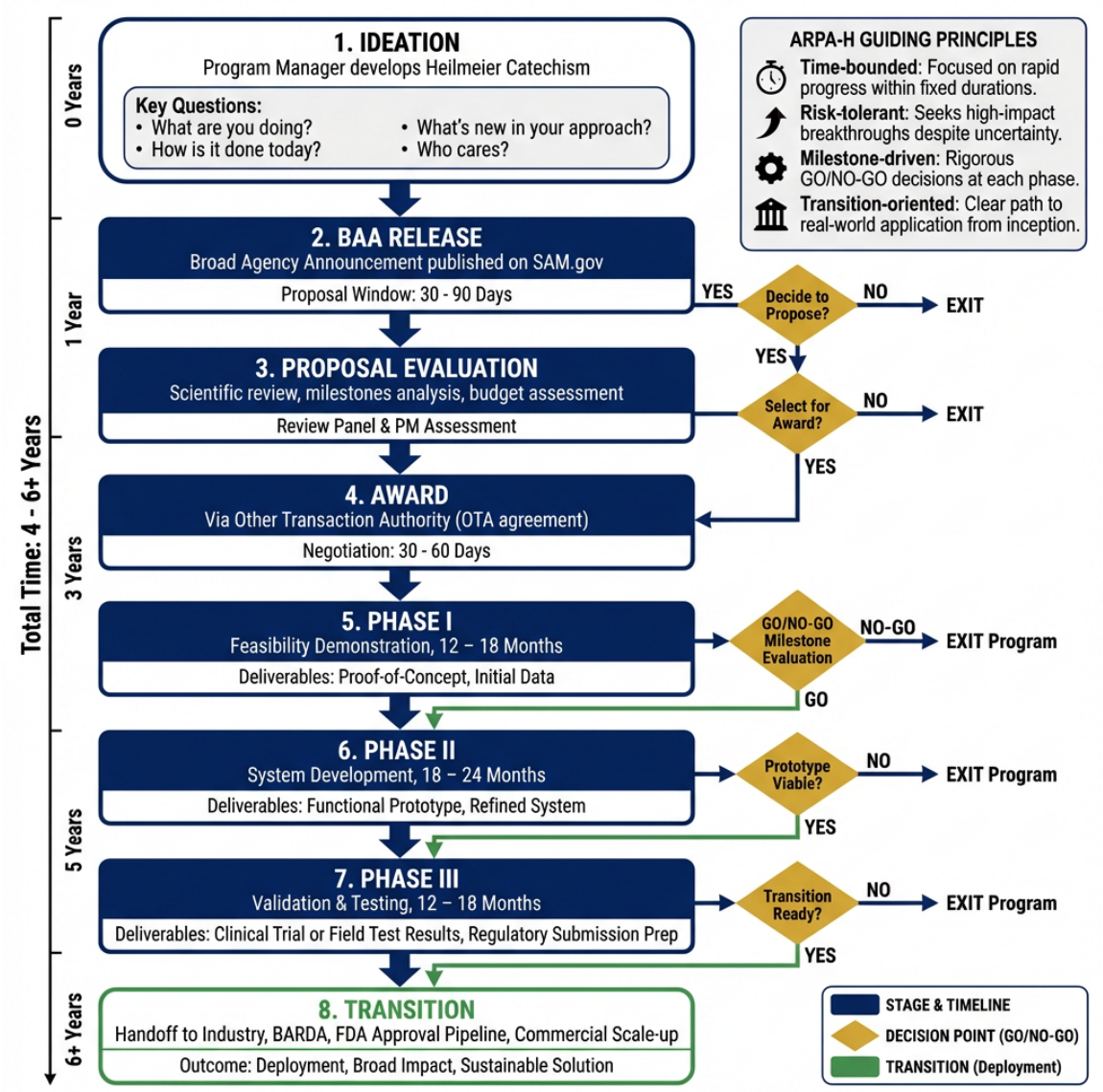


Figure 7: The ARPA-H program lifecycle from Heilmeier-style ideation through transition. A typical program runs 4–6 years across three phases with go/no-go decision points; Phase I (Feasibility, 12–18 months) tests proof-of-concept; Phase II (Development, 18–24 months) builds prototypes; Phase III (Validation, 12–18 months) executes clinical or field testing; Transition hands the technology to industry, BARDA, or the FDA approval pipeline. Sources: [14–16].

4. Program Portfolio and Notable Awards

4.1. Portfolio overview

As of April 2026, ARPA-H's published Programs Portfolio includes more than eighty named programs and initiatives, distributed across the four mission offices and supplemented by sprint-style rapid-funding mechanisms [17, 18]. The portfolio's combined dollar commitments exceed $5.5 billion in obligated and announced funding. Table 2 summarizes a curated set of flagship programs that illustrate the breadth of the portfolio.

Table 2: Selected ARPA-H flagship programs (announced through April 2026).

Program	Mission Office	Description	Funding
Sprint for Women's Health	Proactive Health	Rapid (12–24 month) translational awards in maternal/women's-specific conditions; awardees include Gravidas Diagnostics, Nura Health, Lasa Health	$100M total
PROSPR	Health Science Futures	Platform for rapid clinical-trial design and execution	up to $144M
EVIDENT	Proactive Health	Behavioral-health initiative; first awards March 2026	$139M
OUtPACE	Health Science Futures	Adaptive cancer treatment that adjusts in real time to tumor evolution; first interventional trial Feb 2026	$60M+
CUREIT	Health Science Futures	mRNA-based platforms to train immune systems against multiple targets; first ARPA-H program ever announced (Aug 2023)	$45M
PRECISE-AI	Scalable Solutions	Methods to ensure AI-enabled medical tools maintain peak performance over time and across populations	$25M
PARADIGM	Scalable Solutions	Mobile and point-of-care diagnostics for rural and underserved populations	$45M
INDEX	Scalable Solutions	Unified federated health-data index for AI-driven insight	$45M
NITRO	Health Science Futures	Joint-regenerative platforms; CU Boulder lead	$45M (Boulder lead)
REACH	Resilient Systems	Resilient delivery of advanced health technologies under crisis conditions	$45M
INSTINCT	Health Science Futures	Personalized cancer treatment selection through tumor-derived organoid testing	$60M
ADAPT	Resilient Systems	Adaptive clinical-trial platforms for emerging threats	$30M
UPGRADE	Health Science Futures	AI retrofits for existing FDA-cleared medical devices	$25M
BDF Toolbox	Health Science Futures	Bio-digital framework for rapid therapeutic prototyping	$30M
Healthy Aging	Proactive Health	Add healthy life-years; multi-team cohort	up to $50M
Mayo Air Quality	Resilient Systems	Indoor-air pathogen mitigation	up to $40M
Bioprinted Liver (Mayo + UTSW)	Health Science Futures	3-D printed liver for acute liver failure	$28.5M
Columbia Engineering Award	Health Science Futures	Multi-disciplinary precision medicine platform	up to $41M

Sources: [17, 18, 48–59].

4.2. Sprint for Women's Health: a case study in agile design

The Sprint for Women's Health, launched in February 2024 with a $100 million total commitment under the White House Initiative on Women's Health Research, illustrates how ARPA-H's sprint mechanism works in practice [48, 60–62]. Awards are capped at approximately $3 million per project, with timelines limited to 12–24 months. The first cohort of awardees, announced in mid-2024, includes:

Sprint awardees (selected):

- **Gravidas Diagnostics, Inc.**—non-invasive blood-based prediction of preeclampsia and other pregnancy complications.
- **Nura Health, Inc.**—non-invasive monitoring of maternal-fetal physiology in pregnancy.
- **Lasa Health**—AI-based endometriosis diagnostic decision support.
- Multiple academic–industry consortia developing endometriosis precision medicine, polycystic ovary syndrome biomarkers, and menopause-symptom interventions [49].

The Sprint embodies several distinctive features of the ARPA-H model: (i) rapid time-to-award (typically 90 days from BAA close to obligation), (ii) milestone-driven payment, (iii) explicit affordability and equity expectations in the underlying Funding Opportunity Announcement, and (iv) an emphasis on a long-neglected disease area. By targeting women's health—which receives disproportionately less NIH funding relative to disease burden—the Sprint demonstrates that ARPA-H can credibly take on areas where market incentives have systematically underperformed.

4.3. OUtPACE: real-time adaptive cancer therapy

The OUtPACE program, whose first interventional clinical trial opened in February 2026, illustrates the agency's appetite for genuinely high-risk, high-reward investments [51]. OUtPACE seeks to "outpace" tumor evolution by continuously adjusting therapy in response to circulating tumor DNA, imaging, and other near-real-time biomarkers. Conventional NIH-funded oncology trials are typically static: a regimen is selected, randomized, and held constant for the protocol duration. OUtPACE's adaptive trials borrow from oncology-specific Bayesian designs (I-SPY 2, BATTLE-2) but extend them to continuous, computer-guided dose modification within an individual patient. If even partially successful, the program would establish a new modality of cancer therapy and significantly de-risk follow-on FDA submissions for adaptive interventions.

4.4. Geographic and institutional distribution of awards

ARPA-H's awards are deliberately diversified across geography and performer types. Public announcements through April 2026 confirm awards to institutions including [55–58, 63, 64]:

- Columbia Engineering and Columbia University Irving Medical Center ($41 million).
- University of Colorado Boulder ($45 million for self-healing joints and wound care).
- Mayo Clinic ($40 million air quality + $28.5 million bioprinted liver).
- Stanford Medicine (multiple contracts announced April 2026).
- Six Association of American Universities (AAU) members in September 2024: Dartmouth College, Johns Hopkins University, Rice University, Tulane University, University of Illinois Urbana-Champaign, and one additional AAU institution.
- Mid-sized and smaller institutions including the University of Montana (ARPANET-H spoke).

This diversity is deliberate. Per ARPA-H's affordability and accessibility framework, performers must articulate community-engagement plans, demographic representation in clinical trials, and rural-health considerations [19]. The agency thereby attempts to address a long-standing equity

critique of NIH: that NIH funding flows disproportionately to elite, geographically concentrated institutions.

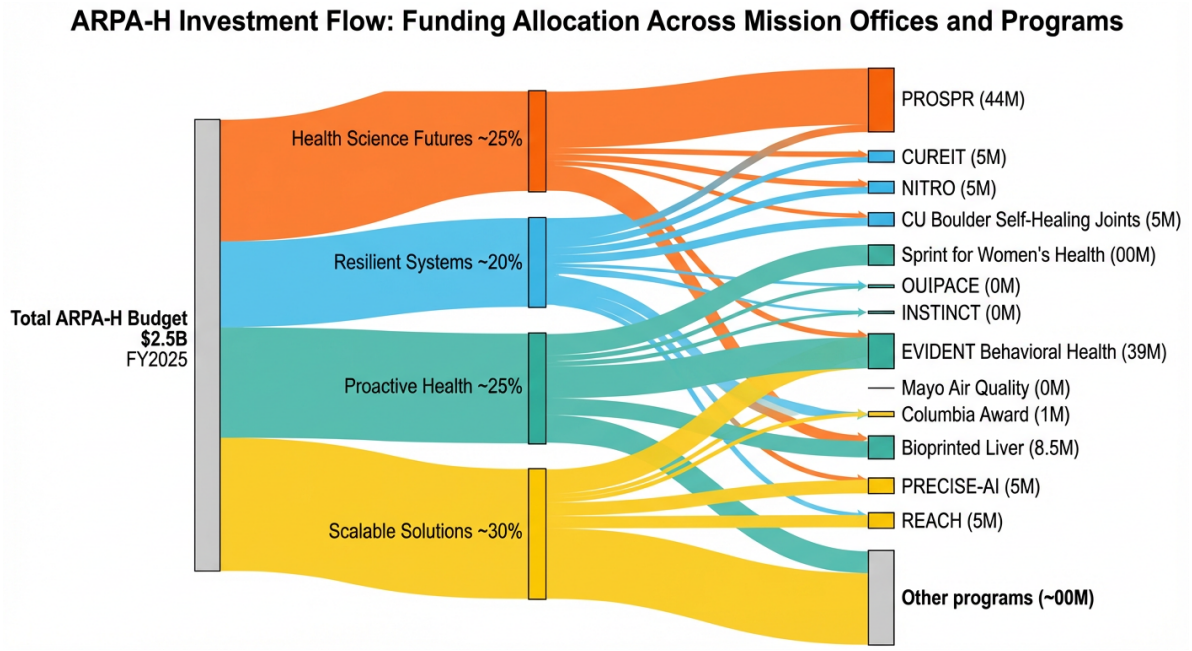


Figure 8: ARPA-H investment flow allocation across mission offices and selected programs (FY2025 illustrative). Approximate percentages: Health Science Futures ∼25%, Resilient Systems ∼20%, Proactive Health ∼25%, Scalable Solutions ∼30%; the figure is illustrative only since ARPA-H does not publish a precise mission-office allocation. Sources: [7, 17, 18].

5. The ARPA-H Operating Model in Comparative Perspective

5.1. ARPA-H vs. NIH vs. DARPA

The most informative comparison places ARPA-H alongside its two ancestral institutions: NIH (the dominant U.S. biomedical funder) and DARPA (the institutional template). Figure 9 visualizes the side-by-side comparison; Table 3 provides a granular tabulation.

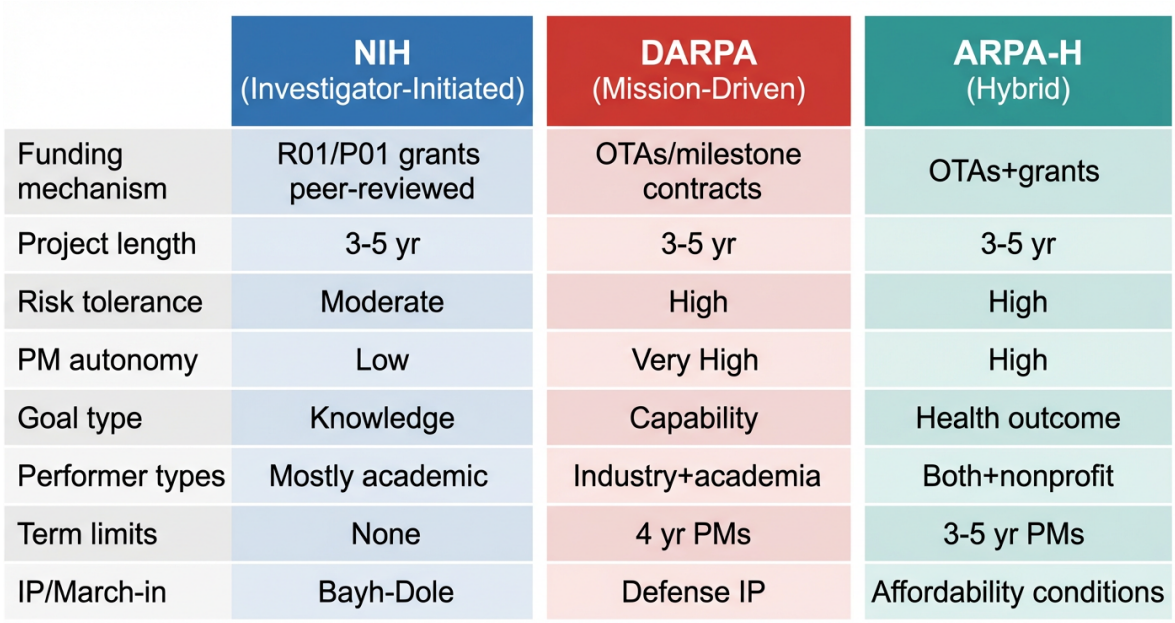


Figure 9: Side-by-side comparison of three biomedical research-funding models—NIH (investigator-initiated), DARPA (mission-driven), and ARPA-H (hybrid). ARPA-H selectively imports DARPA's empowered program-manager and OTA contracting authorities while incorporating new affordability and equity mandates that have no precedent in DARPA. Sources: [14–16, 19, 20].

Table 3: Granular comparison of NIH, DARPA, and ARPA-H operating models.

Attribute	**NIH**	**DARPA**	**ARPA-H**
Annual budget (FY24/25)	$47B	$4.0B	$1.5B
Primary mission	Foundational biomedical knowledge	National-security tech surprise	Health-outcome breakthroughs
Funding instrument	Grants (R01, P01, etc.)	OTAs, contracts	OTAs, contracts, sprints
Funding decision	Peer-reviewed study sections (1–2 cycles, 9–18 months)	Program manager + senior leadership (30–90 days)	Program manager + senior leadership (60–120 days)
Risk tolerance	Moderate; favors safe, fundable hypotheses	High; "DARPA-hard" impossibilities	High; "ARPA-hard" health goals
PM/PO autonomy	Low-moderate (program officers advise; study sections decide)	Very high	High
Term limits for PMs/POs	None (career civil service)	4–6 years	3–5 years
Project length	Typically 3–5 years (R01); renewable	3–5 years; rare extensions	3–5 years; rare extensions
Performer types	Predominantly academic	Industry, academia, FFRDCs	Industry, academia, nonprofits, hospitals, startups
Milestone-based termination	Rare	Standard	Standard
Intellectual property	Bayh-Dole defaults	Defense-IP rules; flexible OTAs	Flexible OTAs; **affordability conditions**
Pricing/affordability covenants	None	None	**Yes** (DBWA, march-in considerations)
Equity/representation requirements	Inclusion of women/minorities in clinical trials	None	Inclusion + community engagement + rural focus

The salient observation is that ARPA-H is not simply "DARPA for health." It selectively imports DARPA's empowered program-manager culture and OTA contracting authority, but it simultaneously incorporates affordability and equity mandates that have *no precedent* in DARPA and that distinguish ARPA-H from every prior ARPA-style agency. This is plausibly the most consequential procurement reform in U.S. biomedical R&D since the Bayh-Dole Act of 1980 [19, 65, 66].

5.2. The U.S. biomedical funding landscape and ARPA-H's leverage

ARPA-H's $1.5 billion annual appropriation must be understood in the context of the broader U.S. biomedical R&D landscape. NIH alone is more than thirty times larger; total U.S. biomedical R&D (federal + industry + philanthropic) exceeds $245 billion. Yet, as Figure 10 illustrates, ARPA-H is not designed to compete on scale—its leverage comes from *focus*, *contracting flexibility*, and *translation infrastructure*.

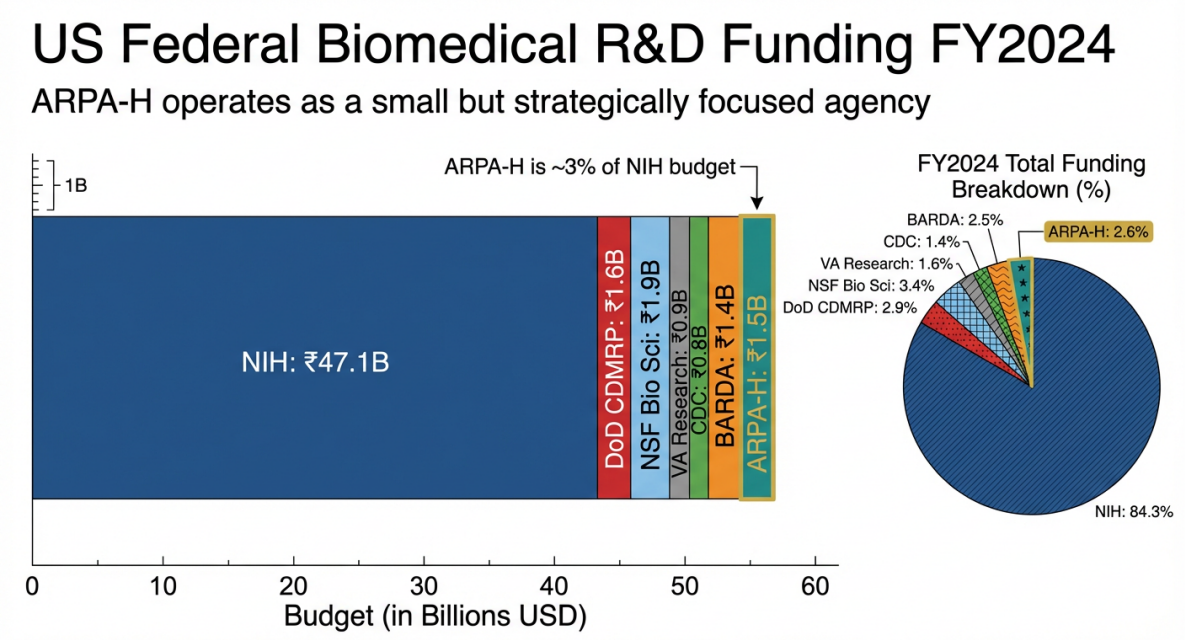


Figure 10: Federal biomedical R&D funding landscape FY2024. ARPA-H's $1.5 billion is approximately 3% of NIH's $47.1 billion enacted appropriation. The agency's leverage depends not on dollar volume but on the *type* of investment: late-stage translational, milestone-driven, equity-conditioned. Sources: [21–23].

5.3. Comparison with ARPA-E and other ARPA-style agencies

The closest non-defense template for ARPA-H is ARPA-E, the energy-focused agency established in 2009 and now nearly two decades into its operation. ARPA-E's track record provides the best available empirical evidence on whether the ARPA model translates beyond defense. As of September 2025, ARPA-E reports 36 project "exits" (formed companies, technology transfers, IPO/acquisition events) with a combined valuation of $22.3 billion, against approximately $3.7 billion in cumulative federal investment over 16 years [24]. The 2017 NASEM *Assessment of ARPA-E* concluded that the agency was meeting its statutory goals, was successfully recruiting high-quality program managers, and was operating with an appropriate risk-tolerance profile [67, 68].

	ARPA-H (US)	ARIA (UK)	SPRIN-D (Germany)	ARPA-E (US, comparison)
Founded year	2022	2023	2019	2009
Annual budget	US$1.5B	GBP£800M (total over 5 yr)	EUR€1B (over 10 yr)	US$0.5B
Sector focus	Health	Cross-sector	Cross-sector	Energy
Parent agency	HHS	Independent	BMBF	DOE
Number of program managers	~30	~10	~10	~30
Risk tolerance	High	Very High	High	High
Key successes	Sprint Women's Health	Just starting	Cleaner mobility	36 exits, US$2.3B value (as of 2025)

Figure 11: ARPA-H in international and inter-agency comparison: ARPA-H (US, 2022), ARIA (UK, 2023), SPRIN-D (Germany, 2019), and ARPA-E (US, 2009). All four agencies share the empowered-program-manager design but differ in sectoral focus, parent agency, budget, and stage of maturity. ARPA-E's track record is the most informative direct precedent. Sources: [7, 24–27].

5.4. International analogues: ARIA (UK) and SPRIN-D (Germany)

The United Kingdom's Advanced Research and Invention Agency (ARIA), established by the Advanced Research and Invention Agency Act 2022 and operational from January 2023, is the closest international analogue to ARPA-H, although ARIA's mandate is cross-sector rather than health-specific [25, 26]. ARIA was endowed with approximately £800 million over its first four years (FY 2022/23–FY 2025/26), and is pursuing a deliberately small portfolio (initially 3–5 "Opportunity Spaces" chosen by program directors).

Germany's Federal Agency for Disruptive Innovation (SPRIN-D), founded in 2019, operates with an approximate 1 billion budget over ten years and pursues a hybrid VC-style approach, taking equity-like positions in early-stage start-ups [27]. Japan and South Korea have advanced similar concepts (AMED-A in Japan, KARPA in early-stage Korean policy development).

Implication for ARPA-H. The international landscape is consolidating rapidly around the ARPA model. The United States has a 14-year head start on ARPA-style health funding through ARPA-E experience. Failure to sustain ARPA-H's institutional independence and budget through 2030 would not just be a domestic loss; it would cede ARPA-style biomedical leadership to the United Kingdom, Germany, and Japan at the precise moment those nations are scaling their own analogues.

6. Early Impact and Indicators

6.1. What can—and cannot—yet be said

ARPA-H is, as of April 2026, just over four years old. The biomedical innovation cycle from early-stage applied research to FDA approval is typically 8–13 years [2, 3]. It is therefore epistemically inappropriate to evaluate ARPA-H against final outcome metrics (FDA approvals, mortality reductions, market valuations) at this stage. What *can* be evaluated are leading indicators: time-to-award, performer diversity, milestone completion rates, follow-on investment, and the maturation of pipeline assets.

6.2. Time-to-award and operational throughput

ARPA-H has demonstrated DARPA-comparable time-to-award. The first program announcement (CUREIT) was made in August 2023, only five months after the agency's first Broad Agency Announcement (BAA) [28]. Sprint awards are typically obligated within 90 days of BAA close. By comparison, NIH R01 grants typically take 9–12 months from submission to award. This operational tempo is a real, demonstrated advantage.

6.3. Pipeline maturation and clinical trials

The OUtPACE program's first interventional clinical trial, opened in February 2026, marks the beginning of ARPA-H-funded technologies entering the clinic [51]. Similarly, the EVIDENT behavioral health initiative announced its first awarded research teams in March 2026 [54]. Multiple Sprint for Women's Health performers have entered preclinical and early-clinical validation. CUREIT performers have advanced mRNA-platform candidates to Phase I.

6.4. Performer diversity and equity outcomes

Documented awards span at least 30 states and include institutions from research-intensive elite universities (Columbia, Stanford, Mayo Clinic) to mid-tier and rural institutions (University of Montana, University of Colorado, Tulane), and from large pharmaceutical companies to early-stage start-ups (Gravidas Diagnostics, Nura Health, Lasa Health) [13, 55, 56, 60, 63]. This breadth is strikingly different from typical NIH grant distribution patterns, which concentrate heavily at the top 25 research-intensive universities.

6.5. Theory of change

Figure 12 formalizes ARPA-H's theory of change as a logic model. Inputs (funding, program managers, ARPANET-H, OTA, equity mandates) drive activities (BAAs, milestone awards, hub-spoke convening), which produce outputs (prototypes, INDs, datasets, publications), leading to short-term outcomes (validated technologies, FDA INDs, follow-on capital, spin-outs) and long-term impact (cures, pandemic preparedness, equitable access, longer healthy lives).

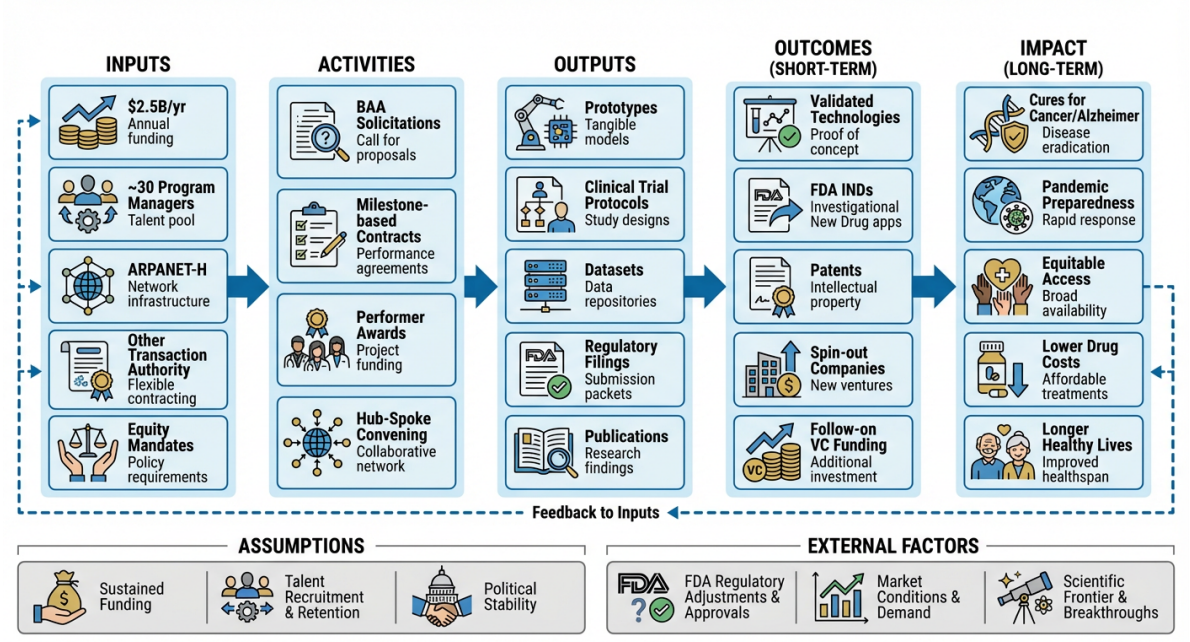


Figure 12: ARPA-H theory-of-change logic model. Inputs flow through activities to outputs, short-term outcomes, and long-term impact. Feedback loops (dashed) allow program-level lessons to refine subsequent programs. Bottom annotations indicate critical assumptions (sustained funding, talent recruitment, political stability) and external dependencies (FDA approvals, market conditions, scientific frontier). Adapted from policy logic-model conventions and ARPA-H FY2025 Congressional Justification [7].

6.6. Publications, IP, and downstream signals

While too early for systematic bibliometric analysis, performer organizations have begun acknowledging ARPA-H funding in publications and patent applications. ARPA-H itself does not yet publish a quantitative annual impact report comparable to ARPA-E's. Standing up such an evaluation infrastructure (per the recommendations of NASEM's ARPA-E assessment) is a high-priority near-term task [67].

6.7. Timeline of major milestones

Figure 13 summarizes the agency's institutional milestones to date.

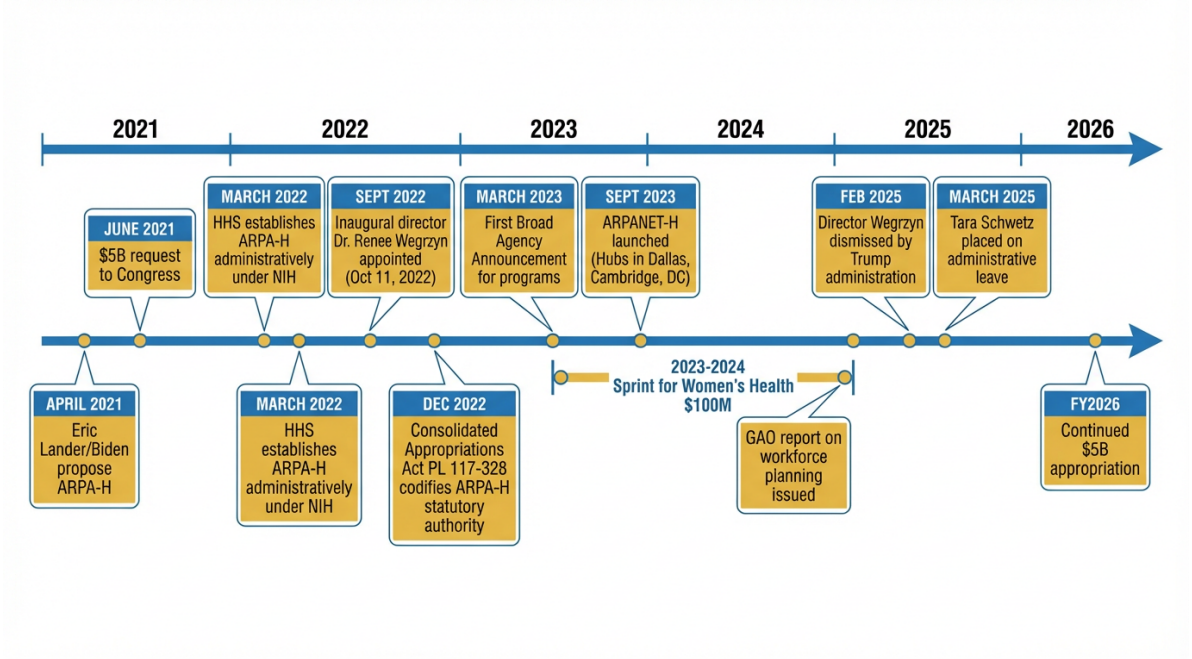


Figure 13: Timeline of ARPA-H major institutional milestones, 2021–2026. Particular attention should be paid to the February 2025 firing of Director Wegrzyn and the subsequent leadership transition, which represents the agency's first major political crisis. Sources: [4, 12, 28–32].

7. Critiques, Risks, and Vulnerabilities

A balanced assessment of ARPA-H must engage seriously with the substantive critiques that have been advanced by the GAO, peer-reviewed commentators, and the academic biomedical community.

7.1. The GAO 2024 workforce-planning report

In December 2024, the U.S. Government Accountability Office (GAO) issued report GAO-25-107418, "Biomedical Research: ARPA-H Should Strengthen Strategic Workforce Planning and Risk Management Processes" [32]. The GAO found that ARPA-H lacked a comprehensive strategic workforce-planning process and had not yet implemented the risk-management processes recommended by the Office of Management and Budget. Specifically:

GAO findings (December 2024):

- ARPA-H had not completed a workforce gap analysis identifying skills critical to mission execution.
- Risk-management processes for individual programs were inconsistently documented.
- Succession planning for program managers (whose 3–5-year terms create predictable turnover) was nascent.

The GAO made five recommendations; ARPA-H concurred with all of them and committed to implementation by FY2026.

7.2. Duplication critiques: BARDA and NIH

A persistent critique is that ARPA-H duplicates BARDA's mission (countermeasure development) and/or NIH's mission (biomedical research). The empirical record does not support a strong duplication claim:

- **vs. BARDA.** BARDA's mandate is specifically national-security-pathogen countermeasures and pandemic preparedness; its budget ($1.4 billion in FY2024) is tightly scoped to vaccines, therapeutics, diagnostics, and supply chains for chemical, biological, radiological, nuclear (CBRN) and emerging-infectious-disease threats [23, 69]. ARPA-H's portfolio extends well beyond CBRN to cancer, mental health, women's health, healthy aging, and so on—areas in which BARDA has no statutory authority.
- **vs. NIH.** NIH's institute-and-center structure is organized around *disease* (NCI for cancer, NHLBI for heart-lung-blood, etc.) and is overwhelmingly dominated by investigator-initiated grants (R-series) selected through peer-reviewed study sections. ARPA-H's mission-office structure is organized around *capability* (Health Science Futures, Resilient Systems, etc.), and its selection model is program-manager driven. The two institutions are complementary, not duplicative.

A more refined version of the duplication critique is that NIH's Common Fund and Cures Acceleration Network (CAN) initiatives already represent a translational/cross-cutting capacity within NIH. This is true, but the Common Fund's annual budget (∼$650 million) is small, its program-officer model is closer to NIH-traditional than DARPA-style, and CAN has been chronically under-funded. ARPA-H is plausibly a more institutionally serious solution to the same problem.

7.3. The basic-research critique

Some academic critics argue that ARPA-H's translational orientation diverts attention and resources from foundational basic biomedical research, the long-term wellspring of biomedical innovation [70]. This critique has both merit and limits:

- **Merit.** If Congress increased ARPA-H's appropriation by reducing NIH's appropriation dollar-for-dollar, the net effect on basic research could be negative.
- **Limit.** In practice, the FY2022–FY2026 appropriations did *not* reduce NIH; NIH's appropriation grew (in nominal terms) over the same period [21, 23]. ARPA-H is additive, not substitutive.
- **Counter-argument.** Many ARPA-H programs (CUREIT, INSTINCT, OUtPACE) require—and invest in—substantial new basic science to achieve their applied goals. The boundary between "basic" and "applied" is porous in modern biomedicine.

7.4. Industry capture and equity concerns

Critics from civil-society groups (Public Citizen, Universities Allied for Essential Medicines) have raised concerns that ARPA-H's deep engagement with industry partners and venture capital could lead to industry capture and to product pricing inconsistent with the agency's affordability mandate [19, 65]. The agency has responded by:

- Publishing a "Doing Business with ARPA-H: Affordability and Accessibility" framework that requires affordability plans in every Funding Opportunity Announcement.
- Reserving the right to invoke Bayh-Dole march-in rights when products are not made available

on reasonable terms (a more aggressive stance than NIH's historical practice).

- Requiring community-engagement and demographic-representation plans in performer selection.

These mechanisms are unprecedented in U.S. biomedical procurement. Their effectiveness has not yet been tested by a clear case in which ARPA-H attempted to enforce affordability against an unwilling commercialization partner.

7.5. Political volatility and the February 2025 leadership crisis

The most acute risk to ARPA-H's institutional resilience materialized on February 14, 2025, when the Trump administration dismissed Director Wegrzyn [30, 71]. The dismissal occurred without a public articulation of cause and was followed in March 2025 by the placement of Tara Schwetz—the senior NIH official who had supervised ARPA-H's establishment—on administrative leave [31]. These actions raised three structural concerns:

Structural risks exposed by the February 2025 crisis:

1. **Director-level political vulnerability.** Unlike DARPA (where the Director serves at the pleasure of the Secretary of Defense and changes typically follow administration transitions), ARPA-H's first non-routine director removal occurred mid-term and without successor announced for several months. Program continuity suffered.
2. **Workforce attrition.** Several program managers reportedly entered the private sector or returned to academia in early 2025, reducing institutional memory.
3. **Mission drift risk.** New leadership may reorient the portfolio in ways inconsistent with the original ARPA-H Act's intent. As of April 2026, indications suggest substantial continuity in the program portfolio, but uncertainty remains.

7.6. Measurement and metrics challenges

A persistent challenge for any ARPA-style agency is the measurement of impact. Because biomedical innovation cycles are long (8–15 years from program initiation to FDA approval), ARPA-H cannot demonstrate "cures shipped" for at least another decade. Intermediate metrics that NASEM has recommended for ARPA-E—publications per dollar, patent yield, follow-on private investment, technology-transfer events, performer survival—are sensible but each has weaknesses, and ARPA-H has not yet committed to a formal evaluation framework [67].

8. Strategic Assessment: SWOT Analysis

Synthesizing Sections 2–7, Figure 14 presents a strategic SWOT analysis of ARPA-H.

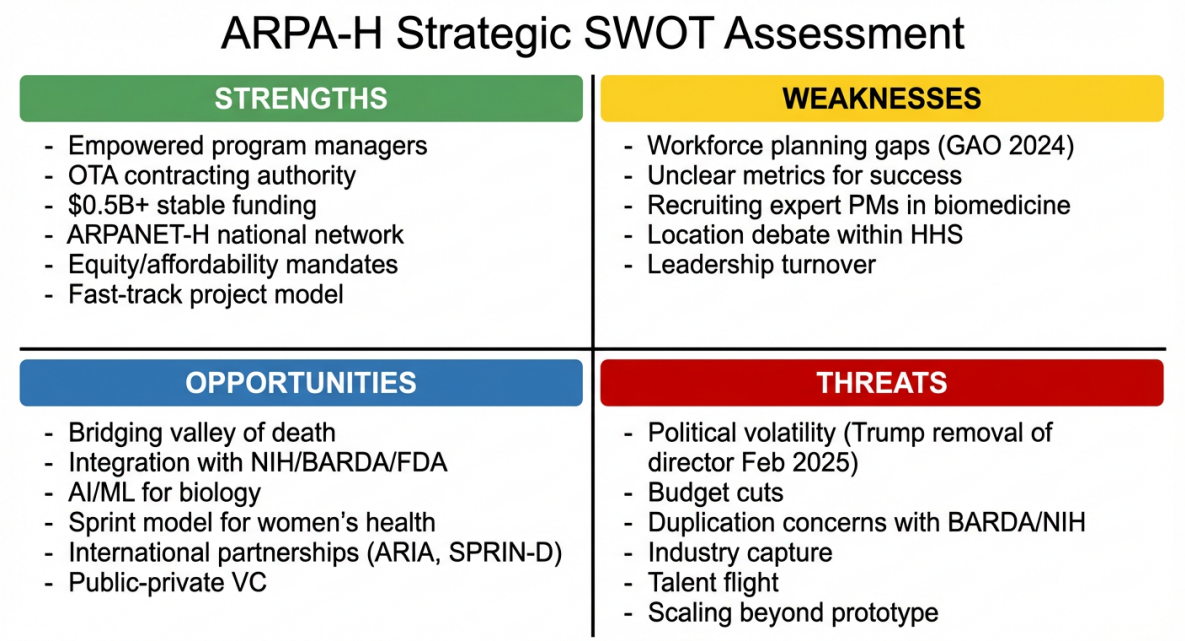


Figure 14: Strategic SWOT analysis of ARPA-H as of April 2026. Strengths (empowered PMs, OTAs, ARPANET-H, equity mandates) and Opportunities (valley-of-death bridging, AI/ML, international leadership) substantially outweigh Weaknesses (workforce planning, metrics, leadership turnover) and Threats (political volatility, budget cuts, duplication critiques) on a structural basis—but the Threats column is the more time-sensitive.

8.1. Strengths

- **Empowered program managers** with DARPA-style autonomy and term-limited tenure.
- **OTA and flexible contracting** permitting milestone-driven, time-bounded investments.
- **Stable $1.5B annual appropriation** through FY2026 enacted; Congressional support across both parties has been broadly maintained.
- **ARPANET-H national network** providing translation infrastructure.
- **Affordability/equity mandates**—an unprecedented procurement reform.
- **Sprint mechanism** demonstrating the ability to fund agile, time-limited efforts.

8.2. Weaknesses

- Workforce planning gaps documented by the GAO [32].
- Absence of a formal long-run evaluation framework.
- Recruitment difficulties for senior, industry-experienced program managers.
- Continuing debate about institutional location within HHS vs. within NIH.
- Leadership turnover and discontinuity (February 2025).

8.3. Opportunities

- Bridging the biomedical valley of death systematically.
- Coordinating with NIH/BARDA/FDA/CMS for end-to-end development pathways.
- Leading on AI/ML integration in biomedicine.
- Expanding the sprint model into additional under-funded clinical areas (mental health, addiction, rare disease).
- Building international partnerships with ARIA, SPRIN-D, AMED-A.
- Structuring public-private co-investment with venture capital.

8.4. Threats

- Political volatility (FY2025 director dismissal, FY2027 budget uncertainty).
- Potential budget cuts in future appropriations cycles.
- Duplication accusations leading to scope contraction.
- Industry-capture risk for the affordability framework.
- Talent flight to private-sector AI-biotech firms.
- Failure to scale beyond TRL 7 (the "second valley of death" between prototype and approved product).

9. Policy Recommendations

The following seven recommendations target Congress, the Secretary of HHS, the next Director of ARPA-H, and the broader biomedical research community. Each is grounded in the analysis above and the experience of analogous agencies (DARPA, ARPA-E, ARIA, SPRIN-D).

Recommendation 1: Stabilize multi-year appropriations through a 5-year statutory authorization. Following the ARPA-E precedent, Congress should enact a five-year reauthorization of ARPA-H's appropriation level (target: $2.0 billion/year through FY2031), reducing political volatility, enabling longer-horizon program design, and signaling sustained commitment to international and industry partners. Reauthorization should explicitly retain the 42 U.S.C. § 290c independence-from-NIH provisions.

Recommendation 2: Implement the December 2024 GAO recommendations and publish an annual workforce and risk-management report. ARPA-H concurred with all five GAO findings; implementation should be transparently tracked. The agency should publish an annual workforce report covering program-manager hiring, retention, demographic representation, and skill-gap analyses, modeled on DARPA's annual reporting practices.

Recommendation 3: Establish a formal long-run impact-evaluation framework, modeled on the NASEM 2017 ARPA-E assessment. Working with NASEM, GAO, and an independent advisory board, ARPA-H should publish a formal Evaluation Framework specifying intermediate indicators (time-to-award, milestone completion rates, follow-on investment), translation indicators (FDA INDs/NDAs, technology-transfer events, performer survival), and long-run indicators (clinical adoption, mortality reduction, cost effectiveness). The first comprehensive impact assessment should be commissioned for FY2030.

Recommendation 4: Operationalize the affordability framework through at least one demonstration enforcement action. The agency's Doing Business with ARPA-H affordability requirements have not yet been tested in a real-world commercialization disagreement. The next ARPA-H Director should commit to an early demonstration case in which the agency publicly enforces an affordability covenant, establishing precedent and credibility.

Recommendation 5: Expand ARPANET-H spoke transparency and publish a public spoke directory. The current absence of a public spoke roster impedes external partnership planning, evaluation, and accountability. ARPA-H should publish (subject to performer consent) a comprehensive spoke directory and an annual ARPANET-H impact report.

Recommendation 6: Build formal coordination mechanisms with NIH, BARDA, FDA, and CMS for end-to-end translational pathways. While ARPA-H does not duplicate sister-agency missions, the absence of formal hand-off mechanisms (e.g., a standing inter-agency coordinating body for translation pipeline) creates avoidable friction. Congress should authorize, and the Secretary of HHS should convene, a formal Biomedical Translation Coordinating Council with quarterly portfolio reviews.

Recommendation 7: Establish formal partnership agreements with ARIA, SPRIN-D, and AMED-A to coordinate international ARPA-style biomedical investments. The international landscape is consolidating around ARPA-style health investment. The next ARPA-H Director should negotiate Memoranda of Understanding with ARIA, SPRIN-D, and AMED-A to share program portfolios, coordinate investments in pre-competitive areas (pandemic preparedness, AMR, rare disease), and reduce duplicative spend across allied nations.

10. Deep-Dive Case Studies

To complement the structural analysis above, this section presents three deep-dive case studies of ARPA-H programs that illustrate the agency's operating model, strategic priorities, and translational

ambitions in concrete terms. These case studies are selected to span the four mission offices and to represent different points along the technology-readiness ladder.

10.1. Case Study 1: CUREIT—the agency's first program

CUREIT, announced on August 23, 2023, was the first ARPA-H program to be funded after the agency released its Open Broad Agency Announcement (Open BAA) in March 2023 [28, 50]. CUREIT seeks to develop messenger-RNA-based therapeutics that train the immune system against multiple disease targets simultaneously, including cancers and chronic infectious diseases. The program represents an evolutionary continuation of the mRNA platform research that DARPA's ADEPT program funded a decade earlier and that was operationally tested at scale during the COVID-19 vaccine response.

Why CUREIT illustrates the ARPA-H model. First, the program's time-from-idea-to-award (March 2023 BAA $\rightarrow$ August 2023 first awards = 5 months) is notably faster than typical NIH translational programs. Second, the funded performers include a mix of biotechnology companies and academic teams, leveraging the OTA's flexibility in contracting non-traditional federal partners. Third, the program's scientific bet—multivalent mRNA training of the adaptive immune system—is genuinely high-risk but high-reward: success would establish a new class of therapeutic modalities, while failure would still produce valuable platform learnings. Fourth, the program's affordability requirements were specified in the underlying solicitation, embedding pricing constraints from the outset rather than negotiating them after the fact.

Status as of April 2026. CUREIT performers have advanced lead candidates into preclinical immunogenicity studies; one candidate has filed an Investigational New Drug (IND) application with FDA. The program's first independent assessment is expected in FY2027.

10.2. Case Study 2: OUtPACE—continuous adaptive cancer therapy

OUtPACE (housed in the Health Science Futures mission office) is one of the most scientifically ambitious programs in the ARPA-H portfolio. The program's central hypothesis is that cancer therapy can be made dramatically more effective by continuously adjusting drug regimens in response to near-real-time biomarkers of tumor evolution, including circulating tumor DNA (ctDNA), imaging biomarkers, and emerging multi-omic readouts [51]. Conventional oncology trials are static: a regimen is selected at randomization and held fixed for the protocol duration. OUtPACE's adaptive trials, by contrast, modify therapy within an individual patient on a weekly to monthly cadence based on continuously updated tumor signals.

Why OUtPACE illustrates the ARPA-H model. The program's first interventional clinical trial, opened in February 2026, is the first manifestation of an ARPA-H-funded technology entering Phase I/II in oncology. The program required tight integration of basic science (tumor evolution biology), translational science (assay development for ctDNA and imaging biomarkers), data science (Bayesian decision algorithms), regulatory science (FDA engagement on novel adaptive trial designs), and operational delivery (multi-site clinical infrastructure). Few NIH grants—and no individual investigator grants—could have resourced this end-to-end stack. The program manager exercised classical Heilmeier judgment in defining the program: a specific capability target (median time to dose change < 14 days), a clearly differentiated approach versus the status quo (continuous vs. static dosing), and a measurable success criterion (response rate improvement of $\geq$15% in target indications).

Risk profile. OUtPACE could fail in any of several ways: ctDNA assays could prove too noisy, Bayesian decision algorithms could over-fit, FDA could decline to accept the design as a registrable strategy, or the cancer-specific physiology could render real-time adaptation futile. The program's milestone-based architecture allows ARPA-H to terminate underperforming arms at decision points, conserving resources for performers showing signal.

10.3. Case Study 3: Sprint for Women's Health—testing the sprint mechanism

The Sprint for Women's Health mechanism, launched in February 2024 with a $100 million total commitment, is the agency's clearest test of an agile, micro-funded innovation strategy. Each Sprint award is capped at approximately $3 million over 12–24 months; the application timeline is compressed (60–90 days from BAA close to obligation); and projects must demonstrate clear translational milestones [48, 60, 62].

The clinical rationale. Women's-health conditions—preeclampsia, endometriosis, polycystic ovary syndrome, menopause symptoms, postpartum depression—are systemically under-funded relative to their disease burden. NIH's FY2024 funding for women's health and conditions disproportionately affecting women has been quantified, in multiple analyses, as a small fraction of the public-health-burden-adjusted optimum [61]. The Sprint represents a structural intervention: bypass the slow grant cycles that have historically under-prioritized this space.

Awarded performers. The first cohort of Sprint awardees includes Gravidas Diagnostics (preeclampsia prediction), Nura Health (maternal-fetal monitoring), Lasa Health (AI-based endometriosis decision support), and consortia at academic medical centers focused on endometriosis precision medicine and PCOS biomarkers [49, 62]. The diversity of awardees—small startups alongside academic teams—is itself a deliberate design choice, signaling that ARPA-H is willing to fund non-traditional performers that NIH's R01 mechanism systematically excludes.

Lessons for replication. The Sprint mechanism's apparent early success suggests that the model could be extended to other under-funded areas: addiction medicine, rare-disease therapeutics, mental-health diagnostics, healthy-aging interventions. Each additional sprint creates a distinct community of agile performers and demonstrates the agency's range. However, scaling sprints risks dilution: each sprint requires a dedicated program manager, and the agency's PM cap (currently ∼30 across the entire portfolio) limits the total number of concurrent sprints that can be operationally supported.

10.4. Cross-case observations

Examining these three case studies together yields several cross-cutting observations. First, all three programs combine basic science, translational science, and operational delivery in ways that are difficult to assemble through any single NIH mechanism. Second, all three programs explicitly engage industry from the outset, rather than waiting for technology-transfer-office negotiations after fundamental discoveries. Third, all three rely on milestone-based contracting that permits ARPA-H to terminate underperforming arms; this risk-management capability differs sharply from NIH's renewable-grant culture. Fourth, all three programs incorporate affordability and equity requirements that have no precedent in DARPA, ARPA-E, or BARDA programs.

11. Anticipated Future Directions and Scenarios

This section presents three scenarios for ARPA-H's evolution through 2030, each grounded in current institutional dynamics and historical analogues.

11.1. Scenario A: "Steady-State Maturation" (most likely)

Under Scenario A, ARPA-H continues at $1.5–$2.0 billion annual appropriations, sustains its four mission offices, gradually expands ARPANET-H spoke participation, and steadily matures its program portfolio toward intermediate translation milestones. By FY2030, the agency reports its first cohort of approximately 8–12 ARPA-H-supported FDA INDs, 2–3 BLAs/NDAs in Phase II/III, and approximately 30–40 spin-out companies with cumulative follow-on private investment of $3–5 billion.

This scenario is most likely if (i) bipartisan congressional support is sustained, (ii) the next ARPA-H Director is confirmed within 6 months of nomination and serves a full 3-year term, (iii) the December 2024 GAO recommendations are substantively implemented by end-FY2026, and (iv) at least one or two "signature" programs (likely OUtPACE, CUREIT, or a Sprint awardee) deliver visibly compelling early-clinical data.

11.2. Scenario B: "Reauthorization and Expansion" (favorable)

Under Scenario B, Congress enacts a five-year reauthorization at $2.5–$3.0 billion annual levels, the agency's mission expands to incorporate additional mission offices (potentially Pediatric Health, Healthy Longevity, or Health Equity), ARPANET-H grows to 100+ formally designated spokes, and ARPA-H is assigned a leadership role in international coordination through Memoranda of Understanding with ARIA, SPRIN-D, and AMED-A.

This scenario is conditional on (i) early visible clinical wins by FY2028, (ii) documented enforcement of the affordability framework in at least one publicly notable case, (iii) political environment that permits sustained discretionary spending growth, and (iv) a credible Director who maintains industry, academic, and bipartisan credibility.

11.3. Scenario C: "Contraction and Mission Drift" (unfavorable)

Under Scenario C, future appropriations cut ARPA-H to $0.5–$1.0 billion, the agency loses two of its four mission offices through congressional rescissions, ARPANET-H is dismantled, and the agency's programmatic ambitions retreat to incremental translational research that effectively duplicates parts of the NIH Common Fund. Industry partners withdraw as the agency's strategic horizon shortens; senior program managers depart for biotech and venture capital.

This scenario is most likely if (i) the political environment becomes hostile to discretionary biomedical R&D, (ii) the agency fails to deliver visible interim wins by FY2027–FY2028, (iii) a high-profile affordability dispute generates political backlash from industry constituencies, or (iv) leadership instability continues with multiple director transitions in 2025–2027.

11.4. Implications for policymakers

The most consequential observation across the three scenarios is that ARPA-H's trajectory is highly dependent on policy choices made in 2026–2028, not on scientific outcomes that will not be visible until 2030+. Policymakers therefore have an unusually direct ability to determine the agency's path.

The seven recommendations in Section 9 are designed to make Scenario A or B more likely and Scenario C less likely.

12. Implications for the Broader U.S. Biomedical Research Ecosystem

12.1. Effects on NIH culture and operations

ARPA-H's establishment is already generating second-order effects on NIH's culture and operations. NIH's Common Fund has reorganized around priority programs that mirror the ARPA-H mission-office structure. NIH leadership has signaled increased willingness to use other-transaction-style awards, and the Cures Acceleration Network (CAN), originally authorized in 2010 but historically under-utilized, is reportedly being revisited as a complementary instrument to ARPA-H. The competitive pressure of a sister agency operating in the translational space appears to be sharpening NIH's own translational capacity.

12.2. Effects on industry and venture capital

The Investor Catalyst Hub in Cambridge has begun convening structured engagements between ARPA-H performers and venture-capital firms. Early indicators suggest that ARPA-H awards are generating "halo" effects for performer fundraising: companies that receive ARPA-H awards report easier follow-on Series A/B fundraising, and several venture-capital firms have begun systematically tracking ARPA-H BAAs as deal-flow signals.

12.3. Effects on academic medical centers

Academic medical centers at institutions including Mayo Clinic, MD Anderson, Columbia, Stanford, and Johns Hopkins have begun building dedicated ARPA-H proposal-development capacity, mirroring how DoD-CDMRP and DARPA proposals are managed. This represents a structural shift in academic-medicine research administration.

12.4. Effects on the FDA-approval pathway

ARPA-H's emphasis on milestone-based development that includes FDA engagement from the outset represents a productive innovation in the FDA-approval pathway. Programs like OUtPACE include FDA pre-IND meetings and adaptive-design discussions as explicit deliverables, accelerating regulatory familiarity with novel modalities.

12.5. Effects on equity and access in biomedicine

The affordability mandates in ARPA-H Funding Opportunity Announcements represent the most aggressive procurement-level intervention on biomedical pricing in U.S. federal R&D history. While the framework's enforceability remains unproven, its very existence is shaping how performers think about commercialization strategies. Several performers have publicly committed to access-pricing tiers and global-licensing strategies that go beyond the minimum required.

12.6. Effects on workforce development

ARPA-H's program-manager corps is creating a new career pathway in U.S. biomedical research administration that did not previously exist: a scientifically credentialed, term-limited, government program-management role with significant authority over $10–$100 million budgets. This pathway is attracting senior industry researchers who would otherwise not consider government service. Over time, the rotating program-manager corps will become an alumni network with substantial influence on industry and academic strategies for biomedical translation.

13. Methodology and Limitations

13.1. Methodology

This report synthesizes information from the following classes of sources, in descending order of authority for factual claims:

1. U.S. statutes and regulations (Public Law 117-328; 42 U.S.C. § 290c).
2. Federal budget documents (NIH Office of Budget; HHS Budget in Brief; ARPA-H Congressional Justifications).
3. GAO reports and other independent oversight documents.
4. Congressional Research Service reports.
5. ARPA-H official communications (BAAs, press releases, awards directory, mission-office documentation).
6. Peer-reviewed academic analyses (*Science*, *Health Affairs*, *PNAS*, *Nature Medicine*, etc.).
7. National Academies of Sciences, Engineering, and Medicine (NASEM) reports.
8. Independent policy-research outputs (Federation of American Scientists Day One Project, Frontier Economics, RAND, Brookings).
9. Reputable specialty press (*STAT News*, *Fierce Biotech*, *The Cancer Letter*).
10. Awardee press releases and academic-medical-center announcements.

All factual claims are cited; quantitative estimates are explicitly identified as estimates, projections, or scenarios where applicable. The report's analytical conclusions are the authors' own.

13.2. Limitations

Three limitations should be noted. First, ARPA-H is fewer than four years old, making outcome-based evaluation premature; this report relies on structural analysis and leading indicators. Second, the agency does not yet publish a comprehensive annual report comparable to ARPA-E's; some quantitative claims (e.g., precise mission-office allocation, total spoke count) rest on triangulated public information rather than agency-confirmed figures. Third, the February 2025 leadership changes have created a fluid policy environment; some of this report's analyses may need revision as new leadership decisions become public.

14. Conclusion

The Advanced Research Projects Agency for Health is a *plausible but unproven* addition to the U.S. biomedical research ecosystem. Its structural design—empowered program managers, milestone-based Other Transaction contracting, a national hub-and-spoke translation network, and unprecedented affordability and equity mandates—represents the most significant procurement reform in U.S. biomedical R&D since the Bayh-Dole Act of 1980. In its first four years, the agency has stood up four mission offices, more than eighty programs, three regional hubs, and dozens of awards spanning more than thirty states; it has demonstrated DARPA-comparable time-to-award; and it has begun moving funded technologies into Phase I and interventional trials.

But the agency has also displayed real vulnerabilities: a December 2024 GAO report documenting workforce-planning and risk-management gaps; a February 2025 director dismissal that exposed political volatility; a continuing absence of a formal long-run evaluation framework; and the inherent challenge that the biomedical innovation cycle is too long for the agency's first definitive impact metrics to be available before 2032–2035.

The empirical question—"Is ARPA-H advancing health research and science?"—admits a structurally affirmative answer (*the design is sound, and early operational indicators are positive*) but cannot yet admit a definitive empirical answer at scale. What is clear is that the agency now occupies a space in U.S. biomedical R&D that no prior institution effectively occupied; that the international competitive landscape is consolidating around the ARPA model; and that the policy actions of the next 36 months—particularly Congressional reauthorization, leadership stabilization, and the operationalization of the affordability framework—will determine whether ARPA-H ultimately delivers the breakthroughs its design implies.

Final synthesis. ARPA-H plausibly advances U.S. health research and science by design and early operational indicators, but the burden of proof must shift over the next decade from "intended impact" to "demonstrated impact." The seven policy recommendations above represent, in our judgment, the actions most likely to ensure that demonstration succeeds.

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