

ARPA-H: The Mission

The Advanced Research Projects Agency for Health

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Collaborative Research on Addiction at NIH
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Overview

- Personal Intro
- Working with NIH
- The Mission
- The Business Model
- Hub & Spoke Model
- ARPA-H Program Managers
- Key Initiatives





ARPA-H: NIH's Newest Partner

Working Together

NIH Collaboration Strengthens Programs during the Entire Lifecycle



DESIGN PROGRAMS

- Work with NIH SMEs to validate well-defined problems in health
- ARPA-H may share select concept ideas with NIH SMEs to help validate that efforts are not redundant and are "ARPA-hard"

BUILD A PERFORMER TEAM

 NIH SMEs may share opportunities with their R&D networks, support proposal evaluation

EXECUTE& MEASURE

 As appropriate, may invite NIH stakeholders to PI meetings for awareness of program approach from Day 1

LEARN & GROW

 NIH colleagues may be transition partners for programs, and remain stakeholders for the duration of the program

COMMERCIALIZE & TRANSITION

- Engage NIH stakeholders who may be appropriate for tech transition as users or funders
- Can formally position NIH as transition partner



ARPA-H & NIH Working Together

ARPA-H & NIH have shared a presence in public events including:

- ✓ Tara and Francis, and many others, helped stand us up!
- ✓ Meeting with IC Directors (11 so far) to share mission, explore working together
- ✓ Milken Health Summit shared panel with Dr. Collins and Dr. Bertagnolli
- ✓ 2022 NIH-Gates Foundation Consultative Workshop
- ✓ Advisory Committee to the NIH Director Meeting
- ✓ Board of Scientific Advisors and National Cancer Advisory Board
- ✓ Non-Dilutive Funding Summit at JPM Health
- ✓ Annual NIA and NIAID meetings
- ✓ NCATS Team tour and brainstorming
- ✓ Shared PM concepts ad hoc with SMEs as applications roll in (thank you for your referrals!)



ARPA-H Kick-Off Event at Howard University



Milken Health Panel



ARPA-H & NIH Future Collaboration

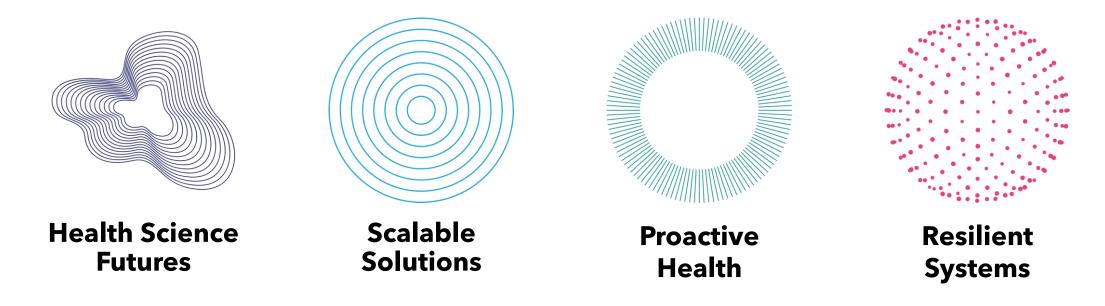
Leveraging our unique organizations to work toward our shared goal of better health for everyone

- ✓ Aiming to meet with all IC Directors and their teams at NIH by Summer 2023 sooner if there is a concept you'd like to immediately engage on!
- ✓ Coordinating small team brainstorming sessions to identify well-defined problems in health that ARPA-H might pursue, including All of Us Research Program, NHGRI, and NIAMS
- ✓ ARPA-H continued engagement with admin functions, admin and research leads meeting with NIH counterparts, including the executive and budget officers
- ✓ More activity at the Program Officer level anticipated as ARPA-H Program Managers onboard





Initial Focus Areas



Additional topics of interest

- Quantitative measurements of health outcomes
- Human-centered design for health innovations
- Participatory research
- Advances in Ethical, Legal, and Societal Implications (ELSI)



Unlock new ways to collaborate and attack problems



Health Science Futures

Expand What's Technically Possible

Develop approaches that bring radically new insights and paradigms. These *innovative* **tools, technologies, and platforms** can apply to a broad range of diseases that affect large populations, rare diseases, or diseases with limited treatment options.

- Novel molecular platform approaches.
 - Modulation of host systems.
 - Delivery to targets with special and temporal precision.
 - Mitigation of off-target effects to accelerate interventions.
- Approaches to accelerate mammalian and microbial cellular engineering to enable next generation therapeutic applications.
- Interventions that target and reverse disease pathogenesis or enhance plasticity to address degenerative diseases.
- Advances in genetic, cellular, tissue, and organ replacement therapies.



Unlock new ways to collaborate and attack problems



Scalable Solutions

Reach Everyone Quickly

Address challenges that include geography, distribution, manufacturing, data and information, and economies of scale to create programs that improve *healthcare access and affordability.*

- Methods to enhance delivery of effective healthcare solutions in rural or low resource settings.
- Innovative manufacturing technologies that reduce cost, shorten production timeline, and eliminate supply chain risk of biologics, cellular therapies, or medical hardware.
- Methods for standardization, automation, and democratization of complex procedures to ensure access and delivery to populations diverse in demographics, geographies, and resources at scale.
 - Histopathology.
 - Rare disease diagnosis and treatment.
 - Surgical interventions.



Unlock new ways to collaborate and attack problems



Proactive Health

Keep People From Becoming Patients

Create new capabilities to identify and characterize disease risk, reduce comorbidities, and promote treatments and behaviors to improve *health and wellness* reducing the likelihood of medical intervention or accelerating recovery and regeneration capabilities.

- Novel techniques to reduce the spread of disease or eliminate risk factors including new vaccine or therapeutic modalities.
- Development of robotics, wearables, and other devices to enhance independence for aging populations and people with cognitive or movement disorders, and to help people age in place.
- Development of novel approaches to continuously measure, analyze, and enhance health-promoting activities to:
 - Accelerate recovery.
 - Enhance immune function.
 - Improve mental health.
 - Treat sleep disorders.



Unlock new ways to collaborate and attack problems



Resilient Systems

Build Robust Health Systems

Create capabilities, develop mechanisms, and accelerate system integrations to enhance **stability and reliability** to weather crises – from the molecular to the societal – such as pandemics, social disruption, climate change, molecular disturbances, and economic instability.

- Novel methods to engineer resilient tissues, microbiomes, and biophysical systems to combat disease or maintain health.
- Novel ways to protect, secure, integrate, analyze, communicate, and present health data.
- Approaches that enable health infrastructure to rapidly integrate commercial-off-the-shelf solutions, create decision support tools, and adapt supply chains, manufacturing, logistics, and strategies to leverage the workforce during public health emergencies.
- Development of novel approaches to address ELSI challenges, patient consent, biosecurity, data reuse and governance, and potential unintended consequences.



Notional Example: Digital Histopathology Capability

Cancer priorities at ARPA-H are cross-cutting within programs

Notional Program Problem:

Current histopathology practice is manual, requires an expert in the loop, is costly, and data is not accessible to share broad insights to improve patient care.

Technical areas include:

- Design and develop novel multi-omic histopath assays
- Al, ML, and data technology for automated diagnostics and 3D tissue characterization
- Data integration into care pathways and digital advocacy

Applications/Indications include:

Proofs of concept for metastatic cancers, neurodegenerative disease, and wound healing



ARPA-H Mission and Business Model

The Promise of ARPA-H

Accelerate better health outcomes for everyone.





President Biden's Vision

"ARPA-H will pursue ideas that break the mold on how we normally support fundamental research and commercial products in this country."

"Ideas so audacious that people say they just might work only if, only if, we could try. Well, we're about to try in a big way."

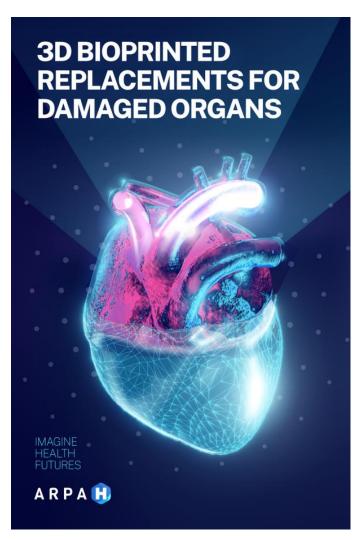
- President Biden Remarks, March 18, 2022

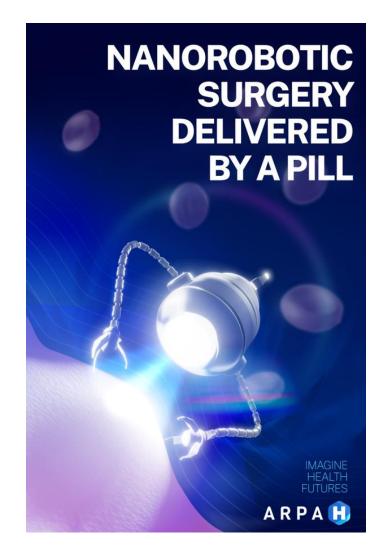




Imagine if...









ARPA-H Timeline

ARPA-H appropriated with a budget of \$1B over 3 years March 15, 2022

Inaugural ARPA-H Director Dr Renee Wegrzyn sworn in October 11, 2022

ARPA-H launches its public presence online November 14, 2022

First solicitations for SETA support and PIA January/February 2023 "OPEN FOR BUSINESS" - ARPA-H launches its first Agency-wide Open BAA, site selection strategy, and Dash to Accelerate **Health Outcomes** March 15, 2023









2023

2022

MAR

APR

JUN MAY

JUL

AUG

SEP

OCT

NOV

DEC

JAN

FEB

MAR

POTUS calls on Congress to fund ARPA-H during SOTU March 1, 2022



ARPA-H established within NIH; Dr. Adam Russell named Acting Deputy Dir May 25, 2022



First event at Howard Univ. October 25, 2022



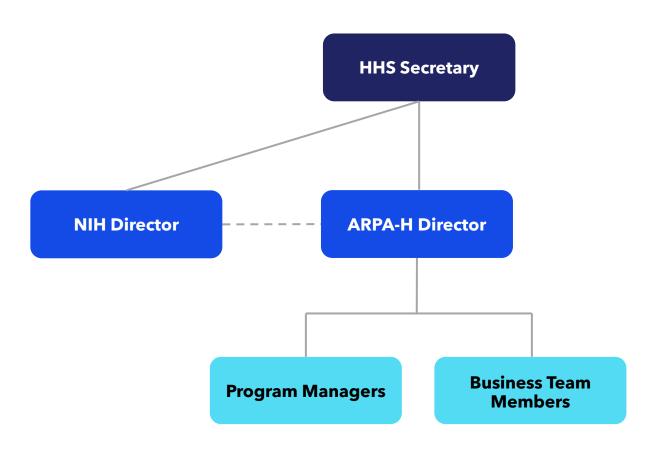
Consolidated Appropriations Act, provides \$1.5B and agency authorities -December 29, 2022



Initial PMs hired and onboarded February 2023



ARPA-H Organization within HHS

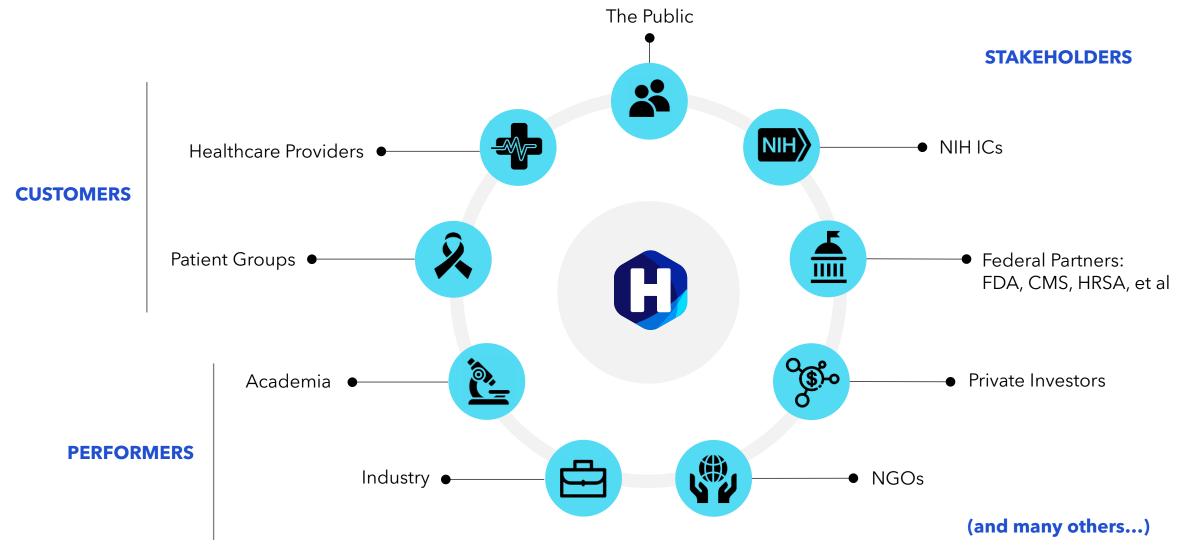


ARPA-H Key Features & Authorities

- ARPA-H is a Federal R&D Funding Agency
- Congress has provided \$2.5B to start; funding independent of NIH
- Independent agency of HHS within NIH, but not an Institute
- ARPA-H Director reports directly to HHS Secretary
- No internal research labs; disease agnostic
- Lean and nimble management structure
- Bottom-up Program Manager driven ideas and decision-making
- Prize Authority
- Not grant-based; focus on Cooperative agreements, OTAs, contracts
- High Risk/High Impact Research

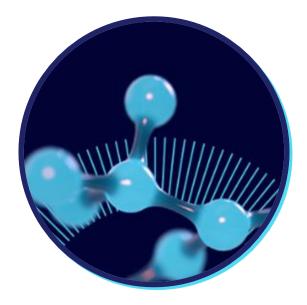


ARPA-H Health Ecosystem





ARPA-H is Open for Business!



First BAA Announcement

ARPA-H opened its first Agency-wide Open BAA, seeking funding proposals for research aiming to improve health outcomes across patient populations, communities, diseases, and health conditions. The BAA calls for proposals to outline breakthrough research and technological advancements.

Open Broad Agency Announcement | ARPA-H SAM.gov



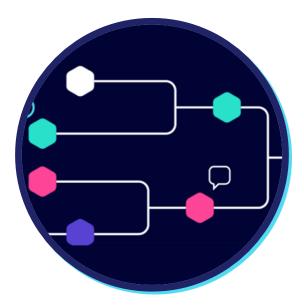


Site Selection

ARPA-H seeks to establish sites in three geographic locations across the United States through the pursuit of a hub-and-spoke strategy. ARPA-H will solicit respondents to identify the geographic locations sites for Hubs No. 2 and 3, issuing a draft Request for Consortium Agreement (RCA), describing the approach to identify the unique locations and capabilities that best serve the ARPA-H mission.

Request for Proposals | ARPA-H & SAM.gov

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ARPA-H Dash

The ARPA-H Dash to Accelerate Health
Outcomes, or "ARPA-H Dash," is launching to
identify revolutionary evidence-based ideas to
transform health. The ARPA-H Dash is a
collaborative online competition open to bold
thinkers across health and scientific
communities and provides a simple, engaging,
and impactful way to solicit the best ideas in the
country to enhance the ARPA-H mission.

ARPA-H Dash | ARPA-H & Online Portal

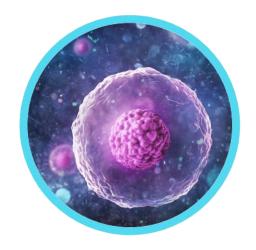
The Program and Program Manager Flywheel



The ARPA-H portfolio is (1) a reflection of the program managers, (2) dynamic, and (3) will - and should! - change frequently



Organizational Attributes



Nucleus of the Organization

Facilitating the Future

Program Managers are the nucleus of the organization, and their energy and passion drive the mission.

ODs and DIRO "work for" the PMs to facilitate success.

PMs are responsible for the full program lifecycle, from new start proposal to transition.



Radical Change

Evolutionary proposers need not apply

ARPA-H investments should seek to address seemingly impossible barriers in demonstrating "proof of concept" for solutions to major challenges – not incremental advances.

Projects should be high-payoff, high-risk, with the most forwardlooking science and technology.



Autonomy

Programs are PM directed

Workshops, consultations, seedlings are encouraged, but no advisory/guidance committees.

PMs should practice "full contact" management, with metrics/milestones for program, empowered to stop underperforming projects.

PMs manage multiple programs, including programs they inherit from departing PMs.



Term Limits

A "projects" agency, not a career

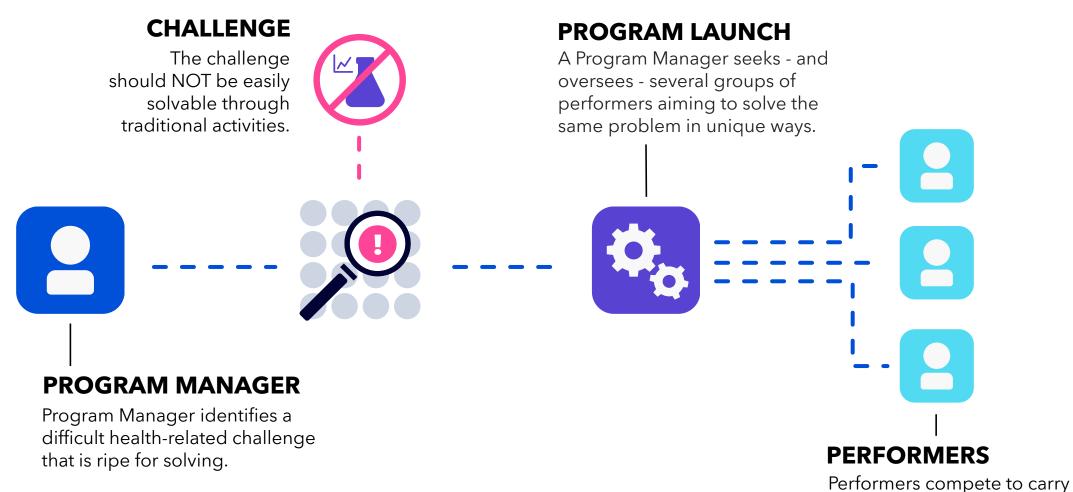
Terms limited to 3 years (renewable once for 6 total years) for PMs, ODs, and DDs, allowing inflow of new ideas.

Limits create urgency and focus on successful NSPs – aligned with office/agency.

Limits remove incentives for empires, organization-building, span of control, bureaucracy, etc.



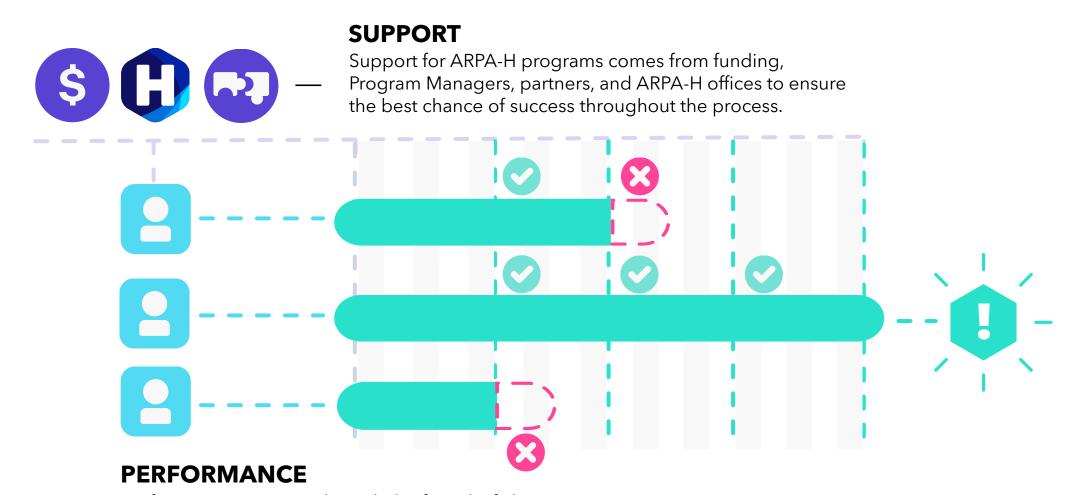
ARPA Model: Program Formation





out their potential innovative solutions to the challenge.

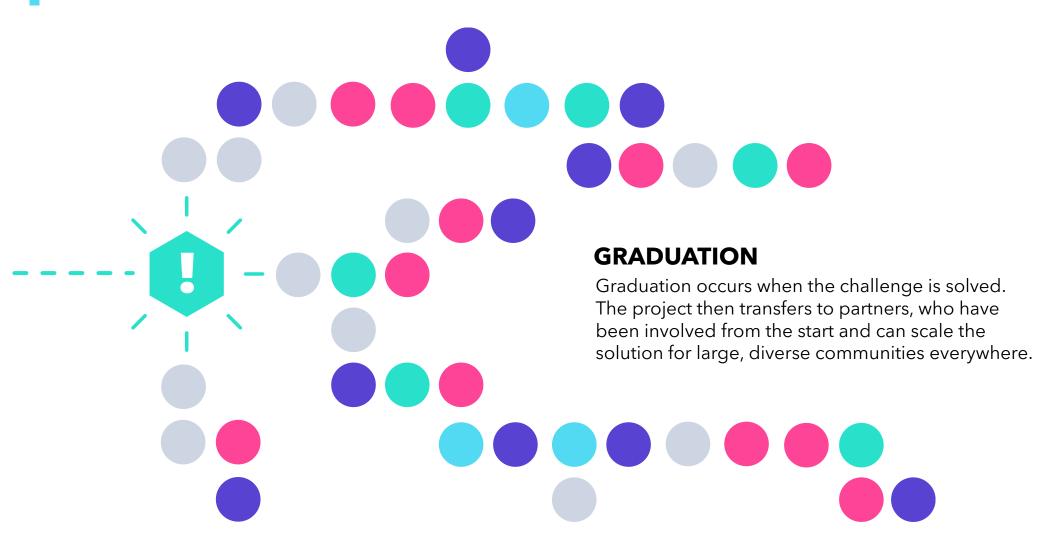
ARPA Model: Support and Evaluation





Performance is assessed regularly. If results fail to measure up, a performer's work may be stopped, while more successful performers continue. Valuable lessons are learned and shared from each project.

ARPA Model: Transition





ARPA-(H)eilmeier Questions

Towards a Well-Defined Problem

- 1 What are you trying to do? What health problem are you trying to solve?
- 2 How does this get done at present? Who does it? What are the limitations of present approaches?
- **3** What is new about our approach? Why do we think we can be successful at this time?
- **4** Who cares? If we succeed, what difference will it make?
- 5 What are the risks? That may prevent you from reaching your objectives? Any risks the program itself may present?
- 6 How long will it take?
- 7 How much will it cost?
- 8 What are our mid-term and final exams to check for success?
- 9 To ensure equitable access for all people, how will cost, accessibility, and user experience be addressed?
- 10 How might this program be misperceived or misused (and how can we prevent that from happening)?



Program Lifecycle

From ideas to solutions in the real world



DESIGN PROGRAMS

- ARPA-Hard and welldefined problems in health
- Heilmeier Framework
- High risk/High consequence
- Stakeholder Insights

BUILD A PERFORMER TEAM

- Solicit Solutions from the community
- Find the best nontraditionals, industry, and academics to solve
- Build new coalitions

EXECUTE& MEASURE

- Active program management against metrics; PM = CEO
- Stakeholder engagement throughout to ensure transition
- Pivot resources when needed

LEARN & GROW

- Capture and share insights
- Technical honesty
- Advance the state of the art; 10x+ improvement, no incremental change

COMMERCIALIZE & TRANSITION

- Assist company formation or licencing
- Provide mentorship, connections to customers, investors
- De-risk investments



Project Accelerator Transition Innovation Office (PATIO)

Increase the probability - at each step - that solutions can "survive in the wild"

PROGRAM LIFECYCLE



PROGRAM DESIGN

- Support PMs to find opportunities and gaps
- Market assessment
- Human-centric design

BAA DEVELOPMENT

- Who are possible performers? Innovation Hubs?
- VC style due-diligence
- Validate transition potential

EARLY PROGRAM PERFORMANCE

- De-risk for investors
- Design MVPs to drive adoption
- Demystify regulatory process

MATURE PROJECTS

- How to protect IP?
- Help company formation
- Business strategy, legal and marketing services

TRANSITION/OUTPUTS SURVIVE IN THE WILD

- SBIR/STTR
- Transition partner/Thirdparty investment
- Ongoing mentorship
- Access to key customers and investors



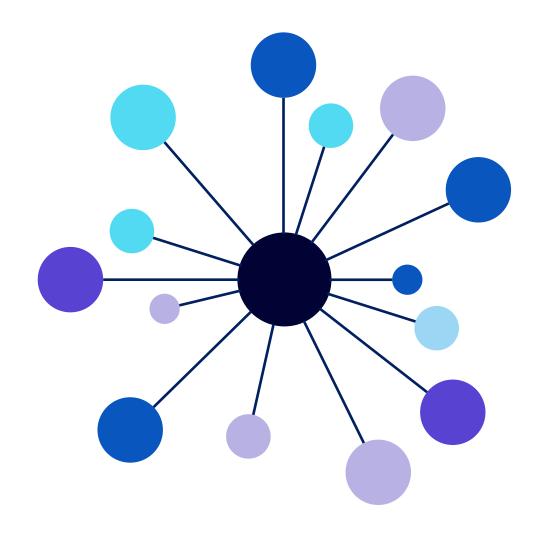
The Hub and Spoke Model

To create a national health innovation network

The 2023 Consolidated Appropriations Act directs the agency to establish sites in at least three geographic areas.

The hub and spoke model will form a **network** of people, institutions, and capabilities across the country.

- Hub: To ensure the active transition of health innovation in an expedient, cost-effective, accessible and sustainable manner that reaches all Americans.
- Spoke: To ensure that Americans in every community benefit from ARPA-H solutions. Spokes are connected to appropriate hubs on an ongoing basis.





Program Managers

What are the Phenotypes?

Uncommon people with common traits

"THINK LIKE A CEO"

RECOGNIZED EXPERTISE

SERIOUS DRIVE



INSATIABLE CURIOSITY

NO FEAR OF FAILURE



INTERDISCIPLINARY TRACK RECORD

TECHNICAL HONESTY



DECISIVE

CUSTOMER-CENTRIC



Different Approaches and Career Stage

THE PROBLEM SOLVER

Motivated by personal experience; can't let it go.

THE DREAMER

Intensely curious about how the world works, motivated by search for objective facts/truth.

THE STATUS QUO CHALLENGER

Early career. Unbiased,

looks at the world with

THE ROOKIE

fresh eyes.

Mid-career. Frustrated by the limits of the existing system.

THE SPRINTER-TINKERER

Intrinsic desire to build and experiment and quickly iterate to achieve path to market. Cares about application, not theory.

THE SAGE

Late career. Experience yields deep understanding.

Becoming a Program Manager

- Responsibility and opportunity to set and maintain a program vision that has the potential to solve a big challenge in health
- Simple but intense application process https://arpa-h.gov/careers/program-managers/
- Timebound (3 yr base contract + up to add'l 3 yrs)
- Competitive salary
- Direct hire, can be "on loan" IPA
- Seeking PMs diverse in geography, demographics, experience, and topic
- Act as "CEO" of their programs and portfolio
- PMs can expect full business and technical team support for day-to-day program management, market assessments, transition, budget, human-centered design, etc.

Application Process

Make contact

Submit a cover letter, CV, and a program concept framed in the ARPA-(H)eilmeier Questions via our website

Talk with us

If the [candidate] + [concept] have ARPA potential, we will reach out to provide feedback the concept, share more about ARPA-H, assess cultural fit, and answer any questions

Prepare to pitch

ARPA-(H)umans will work with the candidate to build an introductory program "pitch" deck that will be the foundation of your ARPA-H interview.

The pitch!

The candidate presents and defends program concept(s) to the ARPA-H team. If selected, the candidate spends 3-4 months once on board to refine the concept, engage key stakeholders, and launch a solicitation to build teams of solvers to address a big problem in health.

https://arpa-h.gov | careers@arpa-h.gov

ARPA-H: The Mission

ARPA-H accelerates better health outcomes for everyone by supporting the development of high-impact solutions to society's most challenging health problems.



Open BAA - calling for proposals to outline breakthrough research and technological advancements



RFI: Accelerating Innovation through ARPA-H and FDA Collaboration - to encourage and incentivize public-private partnerships in the health ecosystem



ARPA-H Dash - launching to identify revolutionary evidence-based ideas to transform health.



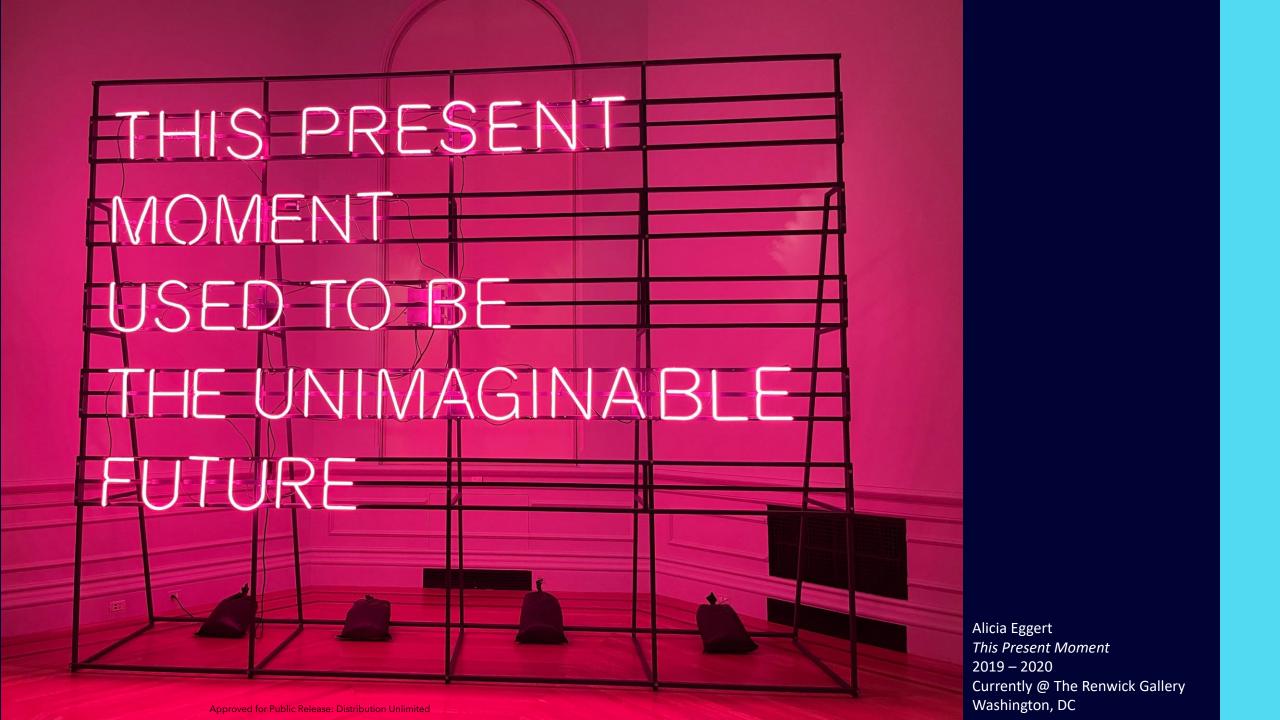
Site Selection - ARPA-H seeks to establish sites in three geographic locations across the United States through the pursuit of a hub-and-spoke strategy.



Our top priority is to **hire the Program Managers** that will bring well-defined problems to ARPA-H and build the teams to solve them.



Apply Now arpa-h.gov careers@arpa-h.gov



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