

ARPA-H: The Mission

The Advanced Research Projects Agency for Health

Jen Roberts, Ph.D.
Director, Resilient Systems

Council of Councils May 11, 2023

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."

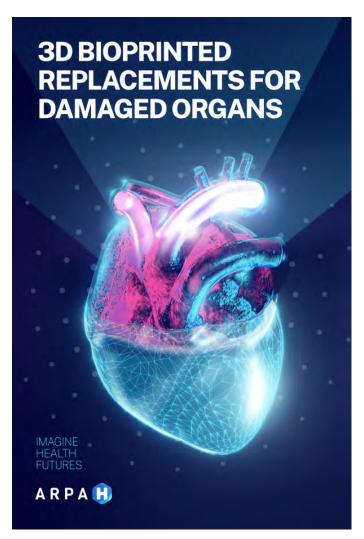
- President Biden Remarks, March 18, 2022

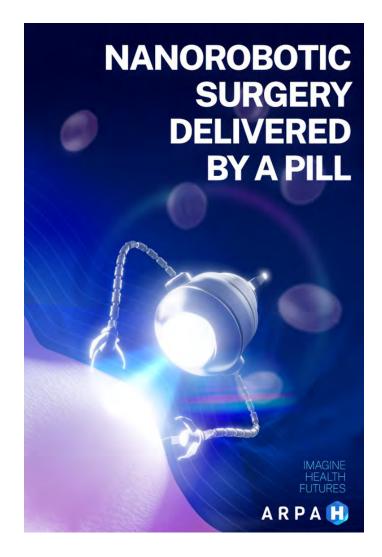




Imagine if...









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

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NOV

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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



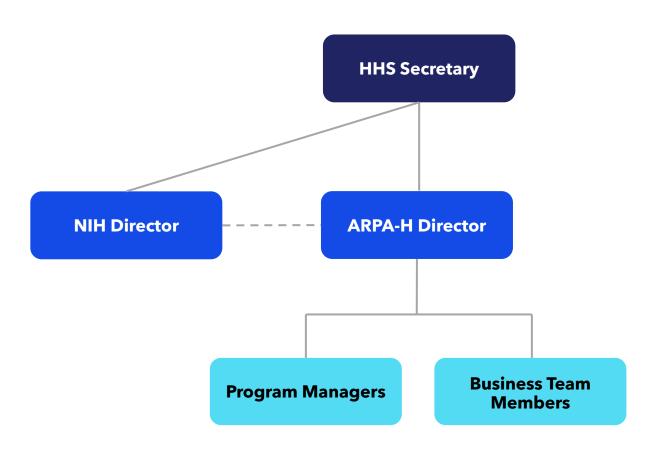
Consolidated Appropriations Act, provides \$1.5B and agency authorities -December 29, 2022



Initial PMs hired and onboarded February 2023



ARPA-H Organization within HHS

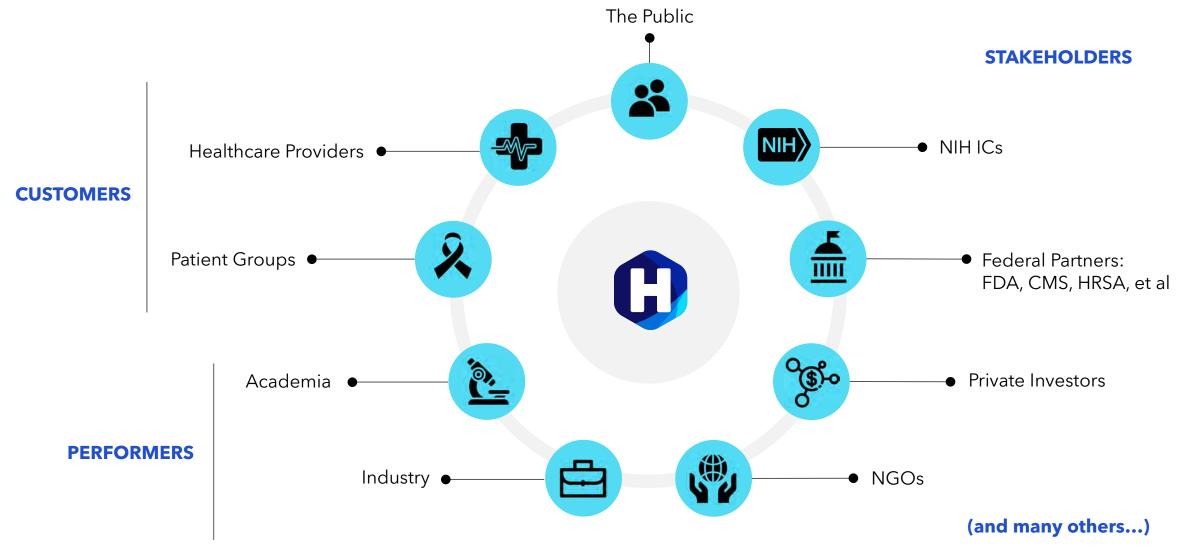


ARPA-H Key Features & Authorities

- 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

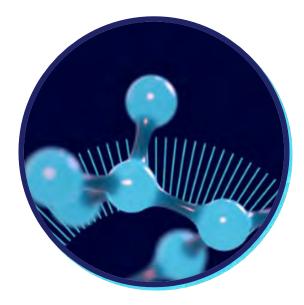


ARPA-H Health Ecosystem





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



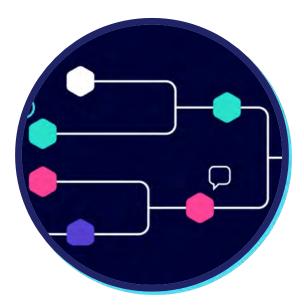


Site Selection

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

Approved for Public Release: Distribution Unlimited



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

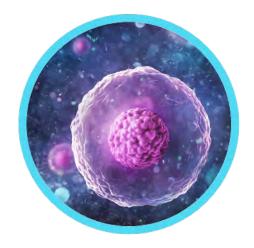
The Program and Program Manager Flywheel



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

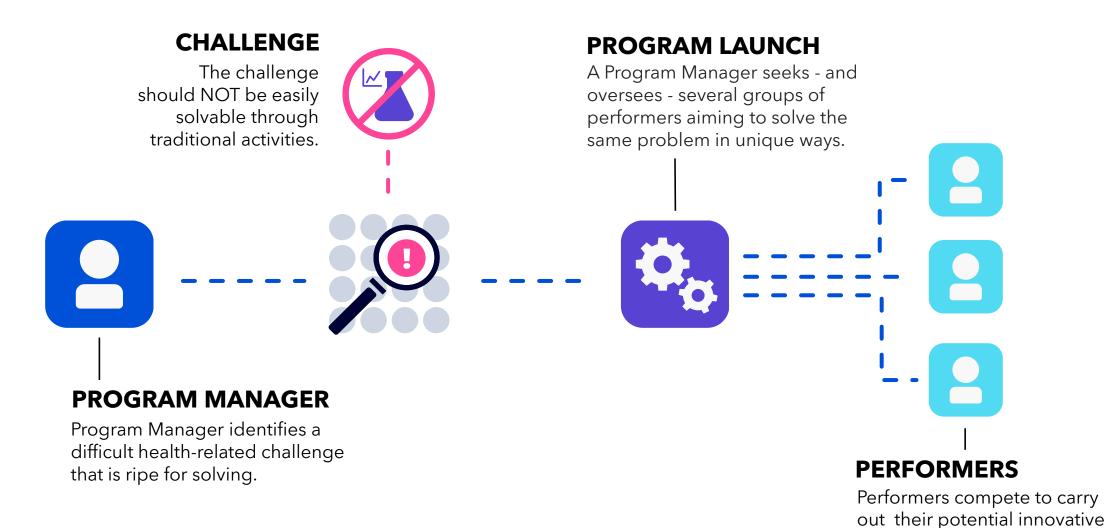
Terms limited to 3 years (renewable once for 6 total years) for PMs, ODs, and DDs, allowing inflow of new ideas.

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

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



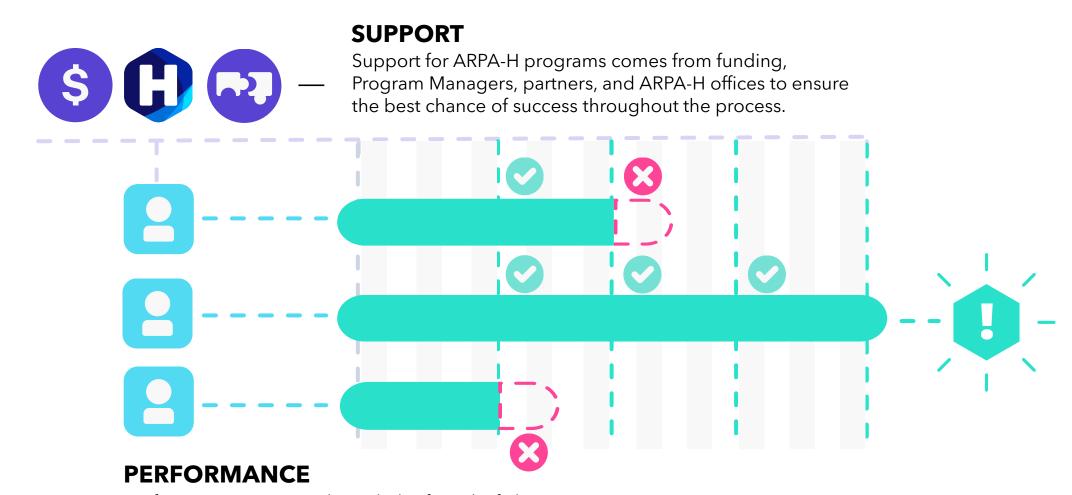
ARPA Model: Program Formation





solutions to the challenge.

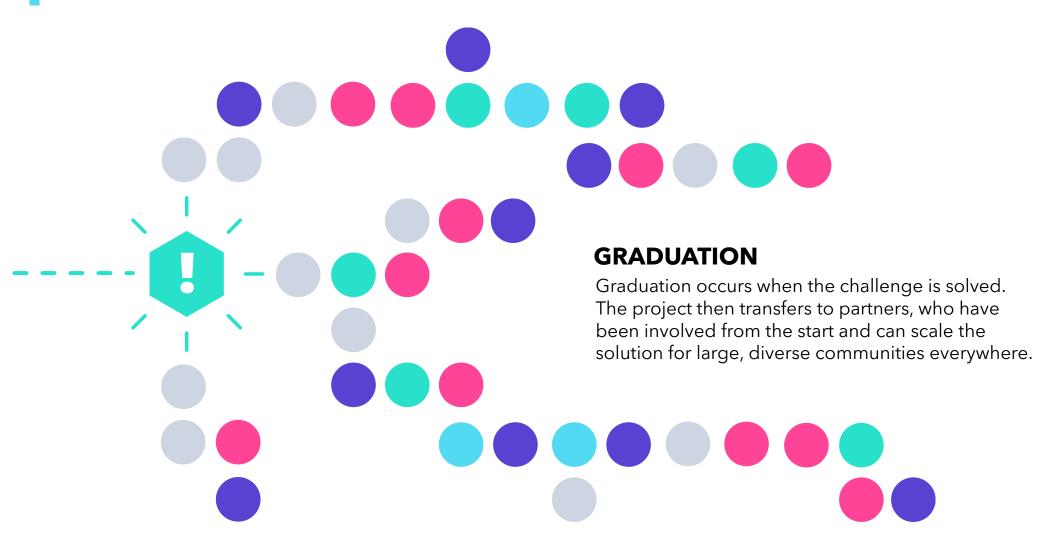
ARPA Model: Support and Evaluation





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

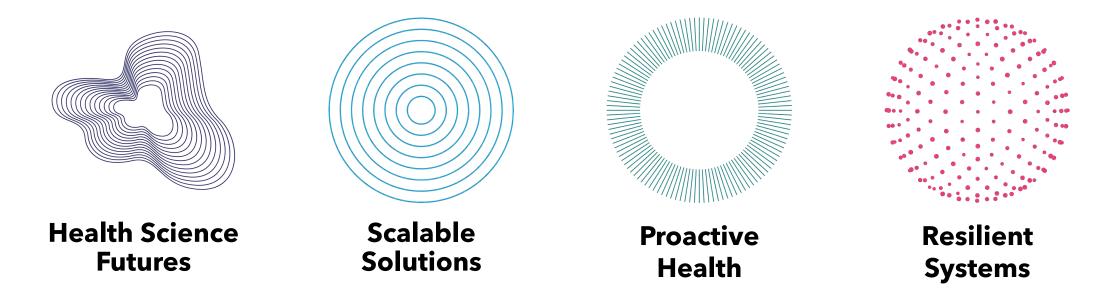
- How to protect IP?
- Help company formation
- Business strategy, legal and marketing services

TRANSITION/OUTPUTS SURVIVE IN THE WILD

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



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.



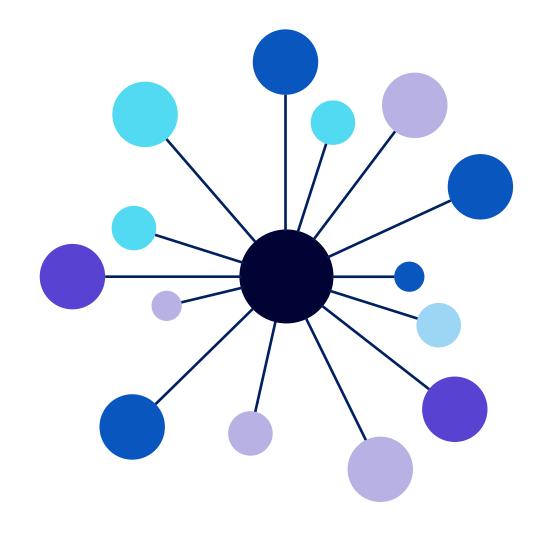
The Hub and Spoke Model

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 SPRINTER-TINKERER

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

THE ROOKIE

Early career. Unbiased, looks at the world with fresh eyes.

THE STATUS QUO CHALLENGER

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

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.



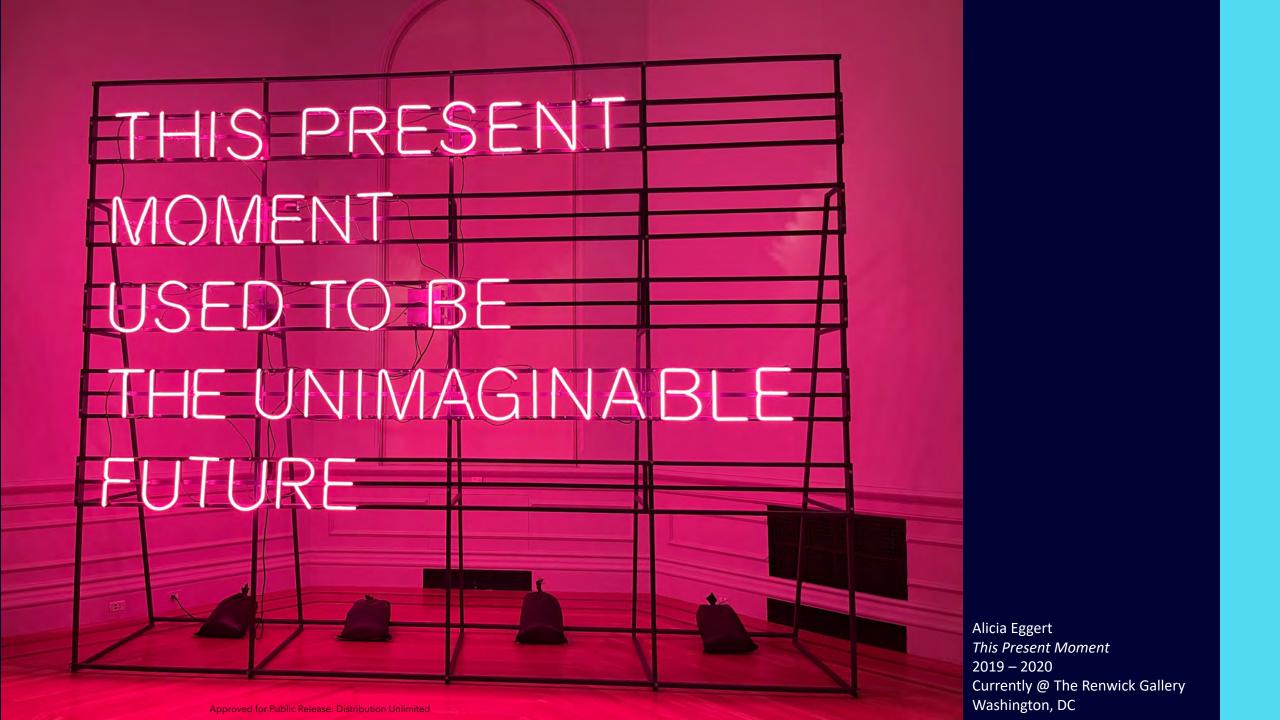
Site Selection - ARPA-H seeks to establish sites in three geographic locations across the United States through the pursuit of a hub-and-spoke strategy.



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





ARPAH

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Additional Questions

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

First solicitations for SETA support and PIA January/February 2023 ARPA-H Celebrates its first birthday! March 15, 2023



OCT



DEC





MAR

MAR APR



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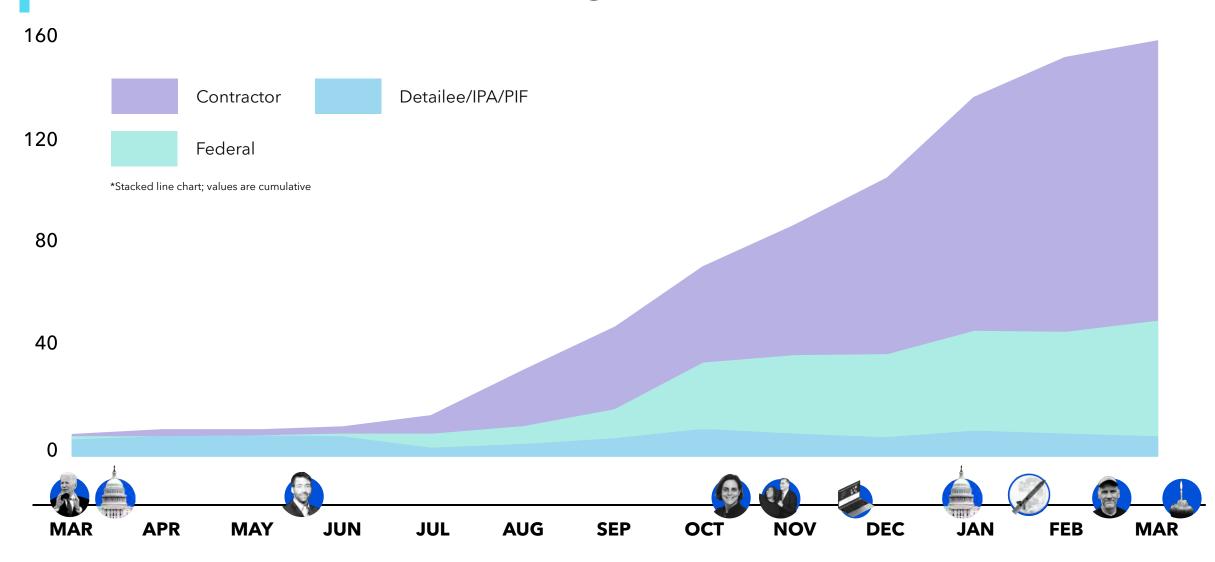


FEB

Initial PMs hired and onboarded February 2023

SEP

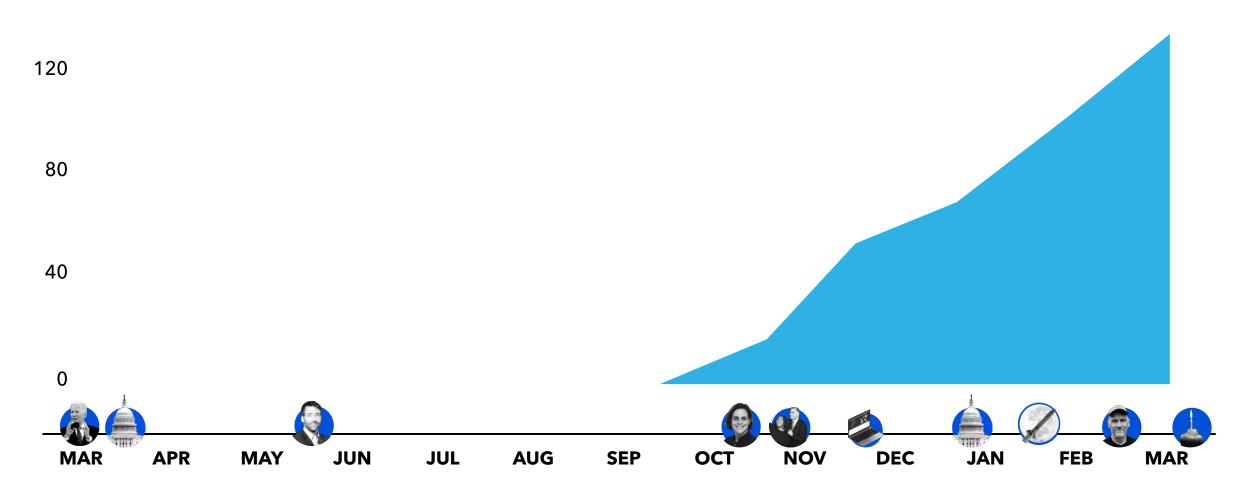
ARPA-H Timeline: Hiring





ARPA-H Timeline: Total Engagements

160





ARPA-H Timeline: Key Hires



Dr. Jen RobertsMission Office Director
Resilient Systems



Dr. Paul Sheehan
Program Manager



Dr. Ross UhrichProgram Manager



Dr. Amy JenkinsMission Office Director
Health Science Futures





Our People. New agency leaders

Dr. Jennifer "Jen" Roberts

Director, Resilient Systems

Jennifer joins ARPA-H as the director of the **Resilient Systems** Mission Office. Previously, she served as the Assistant Director for Health Technologies at the White House Office of Science Policy.

Dr. Ross Uhrich

Program Manager, Health Science Futures

Ross comes to ARPA-H from the U.S. Uniformed Services University, where he was an associate professor of surgery. His research concerns less invasive approaches, including cancer tests that don't rely on biopsies.

Carmelita Chadwick-Gallo

Director, **Comptroller Office**

Carmelita joins ARPA-H as the director of the Comptroller Office. Previously, she was the director of the Research Triangle Park Finance Center for the EPA and a Fellow in the Presidential Leadership Workshop Program.

Dr. Amy **Jenkins**

Director, Health Science Futures

Amy joins ARPA-H as the director of the Health Science Futures Office. Previously, she served as a Program Manager at DARPA, where she explored infectious diseases and novel manufacturing methods to enable rapid response.



Dr. Paul Sheehan

Program Manager, Resilient Systems

Paul joined ARPA-H from DARPA, where he worked as a Program Manager in the Biological Technologies Office. His research leverages synthetic biology to detect and correct a wide range of threats to human health.

Dr. Joe **Shonkwiler**

Chief Operations Officer

Joe joins ARPA-H as the Chief Operations Officer. He hails most recently from AWS, is a physician and MBA with experience in clinical medicine, digital health ventures, business development, health policy, and clinical outcomes research. He hosts AWS' Health Innovation Podcast.





COMING SOON!









1 Year From Now

15 - 20 PMs

Grow our technical team and portfolio

4 Mission Office Directors

Leadership team in place

We're scaling

Still in high growth phase, but matured with robust processes to support all functions

We're specific

We have programs launched that we can point to in depth that demonstrate the ARPA model at work

Data Layer

We've built our data team and the organizational infrastructure for data-driven business and technical work.

We're obligated

In the fiscal sense - we are spending our budget on impactful projects and continue to grow our team and work

We're cultured

We've harnessed that ARPA attitude, ambition, and fearlessness that are the cornerstone for ARPA culture





5 Years From Now

100 PMs

Continuing to grow our technical team and portfolio, transitions and solutions ready for market

We've transitioned

The first PMs may now be alumni, and the first projects have successfully transitioned

We are still scaling

Our processes support continued growth, efficiency, and scalability in critical areas; more mission amplification

Data Layer

We are an organization where data drives all business and technical work and measures health outcomes

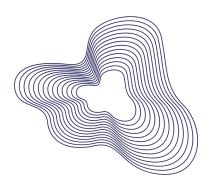
We're agile

In addition to investments in our dynamic program portfolio, we are prepared to invest in emerging technologies and solutions that help our nation face our next crisis in health – whether it be caused through pandemics, economics, or climate





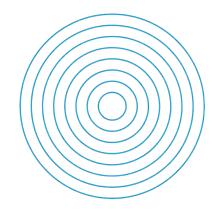
Initial Mission Focus Areas



Health Science Futures

Expanding what's technically possible

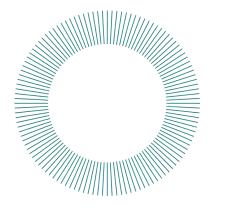
Accelerate advances across research areas and remove limitations that stymie progress towards solutions. These tools and platforms apply to a broad range of diseases.



Scalable Solutions

Reaching everyone quickly

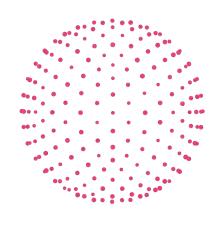
Address health challenges that include geography, distribution, manufacturing, data and information, and economies of scale to create programs that result in impactful, timely, and equitable solutions.



Proactive Health

Keeping people from being patients

Preventative programs will create new capabilities to detect and characterize disease risk and promote treatments and behaviors to anticipate threats to Americans' health, whether those are viral, bacterial, chemical, physical, or psychological.



Resilient Systems

Building integrated healthcare systems

Create capabilities, business models, and integrations to weather crises such as pandemics, social disruption, climate change, and economic instability. Systems are sustained between crises—from the molecular to the societal—to achieve better health outcomes.



Project Accelerator Transition Innovation Office (PATIO)

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

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PROGRAM DESIGN

- Support PMs to find opportunities and gaps
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- De-risk for investors
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MATURE PROJECTS

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

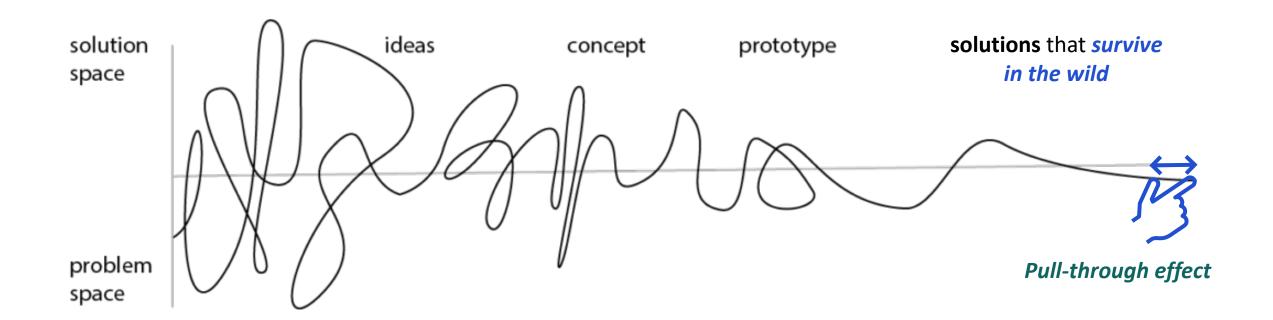
TRANSITION/OUTPUTS SURVIVE IN THE WILD

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



Unique Capability: Concepts from inside and outside government

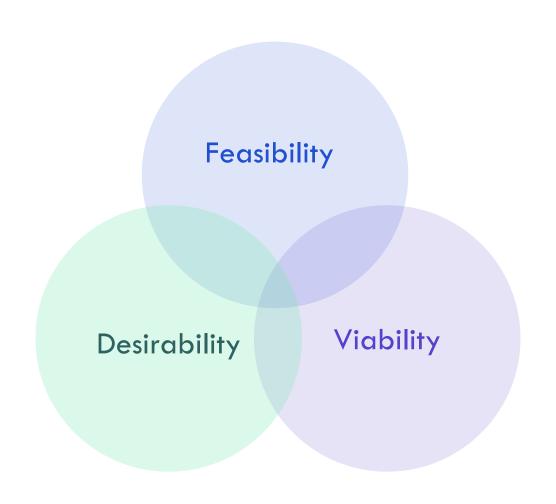
150+ structured interviews w/ ARPAs, BARDA Drive, tech transfer offices, investors, accelerators, incubators...





Unique Capability: Concepts from inside and outside government

150+ structured interviews w/ ARPAs, BARDA Drive, tech transfer offices, investors, accelerators, incubators...





Public/Private Partnership: Leverage private sector experts

Increase viability: first collection of core tools



Allows ARPA-H to obtain highly specific and customized services to support ARPA-H, PMs, and their programs for commercialization and transition

Agency & Mission Office Analysis

- How can the government de-risk novel solutions so the private sector will adopt them?
- Mission Office HorizonScanning

PM and Program-Focused Analysis

- Emerging trends
- Major failures within the past 5-years
- Identify key stakeholders

Program Support

- Test out rapid transition ideas
- Collider Days
 & SBIR/STTR
 support

Experts in Residence (XIRs):

- Tech to market analysis
- Develop commercializa tion milestones
- Regulatory assessments
- Mentorship



Be-Spoke and Hub Model. Meet Americans Where They Are...

A nation-wide health innovation network

Hub and Spoke Model:

Ensure Americans in every community benefit from ARPA-H solutions. Americans can either be current patients or healthy people who seek to increase their healthspan.

Our three sites are centers of gravity, but not the whole network...

Represent the core capabilities and ongoing agency needs required to successfully launch and transition programs. Will connect with spoke partners in various locations in many states: urban, rural, etc.

Site 1: Federal Stakeholders & Operations

(TBD in DC metro area - not competed)

Feasibility

Site 2: Customer Experience Hub

(TBD - competition)

Site 3: Investor Catalyst Hub

(TBD - competition)

Desirability

Viability



PMs Define Success for Future Real-World Impact

At ARPA-H, our Program Managers identify a well-defined problem to pursue through the program life cycle to bring solutions forward that:



"Survive in the wild"

Real people **want** them and enthusiastically **adopt** them.



Separate the improbable from the impossible

Remove the barriers of today's technologies and systems.



Deliver better health to everyone

The healthy, the sick, providers, hospitals, all 50 states, the world...

Program Managers will use flexible contracting vehicles, including Cooperative Agreements, Contracts, and Other Transactional Authorities to create these solutions.



Recent ARPA-H Milestones

- ✓ First PMs onboarding in Q1, first programs in Q2/Q3 2023
- ✓ Released Partnership Intermediary Agreements (PIA) Solicitation
- ✓ Coast to Coast engagements with:
 - More than 35 members of Congress, staff, and intragovernmental partners
 - More than 50 universities' administrators, vice chancellor/vice presidents of research and associated faculty
 - More than 100 patient advocacy organizations and professional associations





arpa-h.gov landing page



J.P. Morgan Event, Jan. 10



"Full Contact" Program Management

- Responsibility to identify well-defined problems in health and assemble teams from industry, academics, and government to solve
- Acts as the CEO of Programs has autonomy as a decision-maker; protects risktaking by ensuring all decisions are made on technical merit, mission benefit
- Develops well-structured programs that decouple concept risk (high) with execution risk (moderate)
- Provides active and cooperative oversight and direction of all programs and performers
 - Define technical milestones/deliverables
 - Monitor technical milestones/deliverables
 - Pivot resources as needed
- Expected to launch ~1 program/year
- Lead a contractor SETA team to execute day-to-day activities

- Stakeholder Engagement
- Budget management
- Drive towards transition





Our Vision Solutions to preserve and expand health

Our Moment

We live in an era of complex technologies with massive economic and social disruptions. Powerful biological factors include pandemics that make us sick and emerging biotechnologies to make us well.

Our Promise

ARPA-H Program Managers (PMs) design, build, and launch **solutions** to create the best version of our health future.

