ARPA-H: The Mission

Advanced Research Projects Agency for Health (ARPA-H)

Jennifer Roberts, Resilient Systems Office Director June 16, 2023

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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."

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- President Biden Remarks, March 18, 2022



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Mission

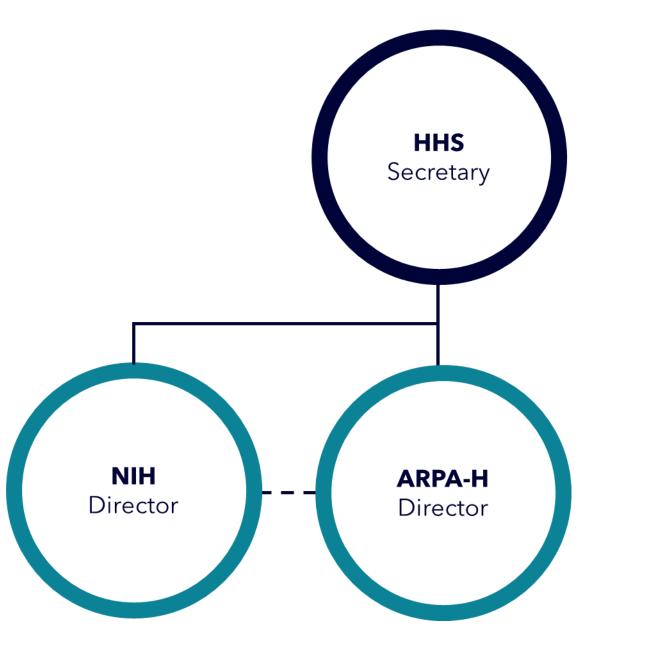
Accelerate better health outcomes for everyone.





ARPA-H Organization within HHS

- Independent component of HHS within NIH; not an Institute
- ARPA-H Director reports directly to HHS Secretary
- No internal research labs; disease agnostic
- \$2.5B initial appropriation; budget independent from NIH
- Generally funds contracts, not grants
- Ability to directly reimburse FDA





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ARPA-H Key Features and Authorities

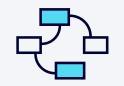
ARPA-H has unique structures and legal authorities that allow it to **function like a business – quickly, nimbly, and decisively**.



Bottom-up decisionmaking. PMs have autonomy to make decisions quickly. ARPA-H is a problems focused organization



Accelerated contracting mechanisms that allow ARPA-H to quickly go from approval to contract.

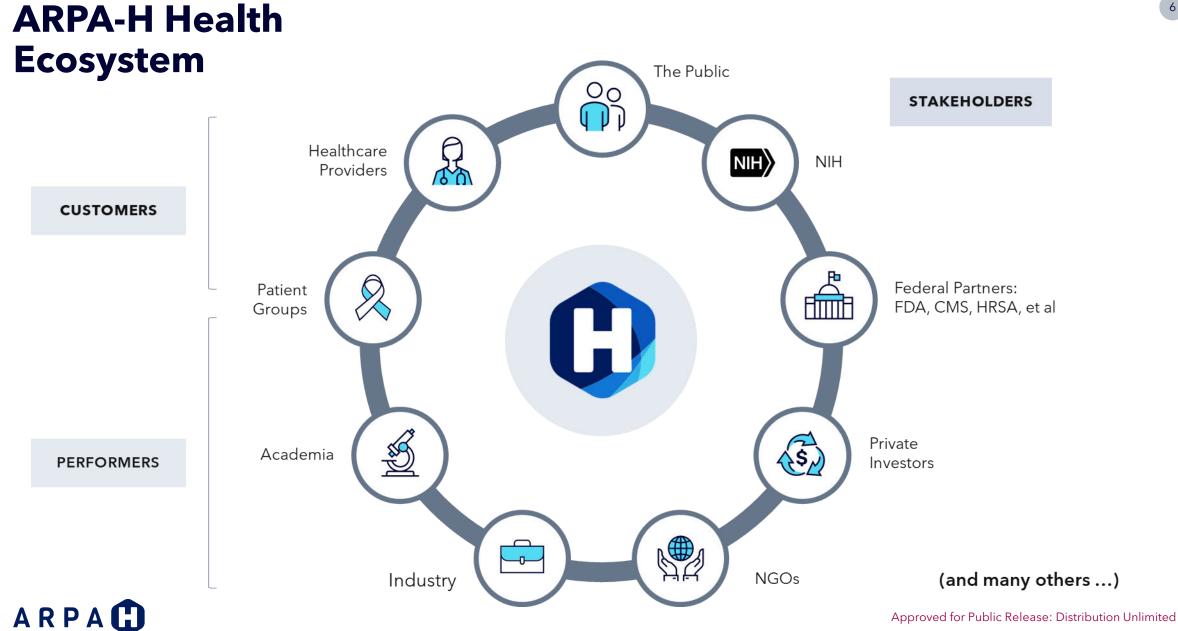


Lean and nimble management structure with autonomy in decision-making.

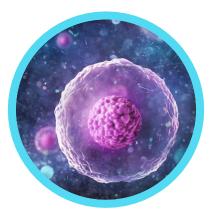


Flexibility in hiring that allows ARPA-H to compensate top performers at levels competitive with industry.





Organizational Attributes



Nucleus of the Organization

Facilitating the Future

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

ARPA-H leadership "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

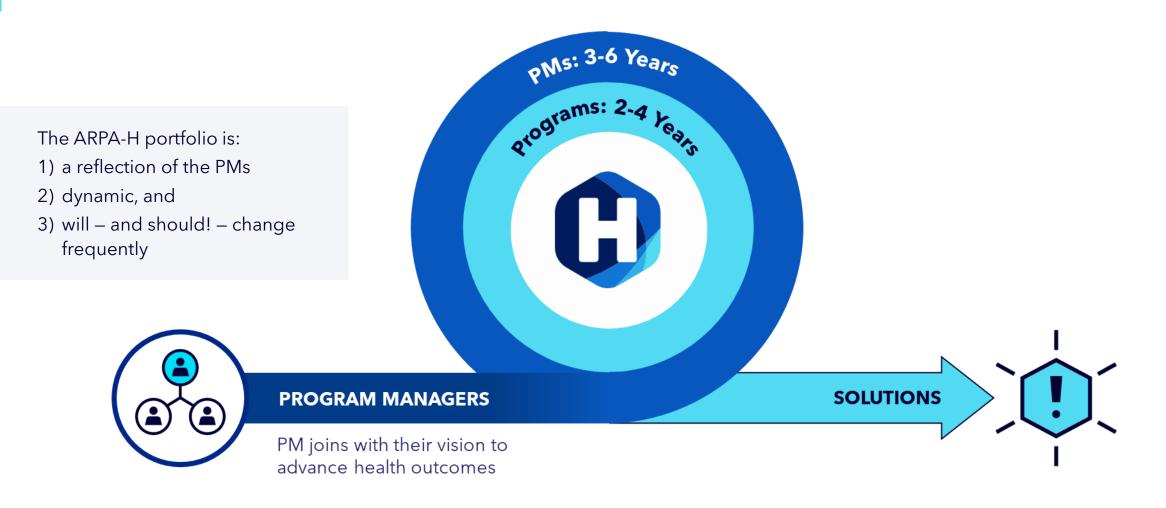
Terms limited to 3 years (renewable once for 6 total years) for PMs, Office Directors, and Deputy Directors, allowing inflow of new ideas.

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

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



The Program and Program Manager Flywheel





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Program Managers

What are the phenotypes?

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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	
Decisive	Customer-Centric	

Different Approaches and Career Stage

The Problem Solver

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

The Rookie

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

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The Dreamer

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

The Status Quo Challenger

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.

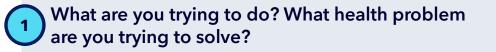
The Sage

Late career. Experience yields deep understanding.



ARPA-(H)eilmeier Questions

Towards a well-defined problem





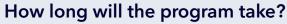
What is new about our approach? Why do we think we can be successful at this time?

Who cares? If we succeed, what difference will it make? What Health Outcomes are we accelerating?



What are the risks? That may prevent you from reaching your objectives? Any risks the program itself may present?

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How much will the program cost?



What are our mid-term and final exams to check for success?



To ensure equitable access for all people, how will cost, accessibility, and user experience be addressed?



How might this program be misperceived or misused (and how can we build trust and prevent that from happening)?



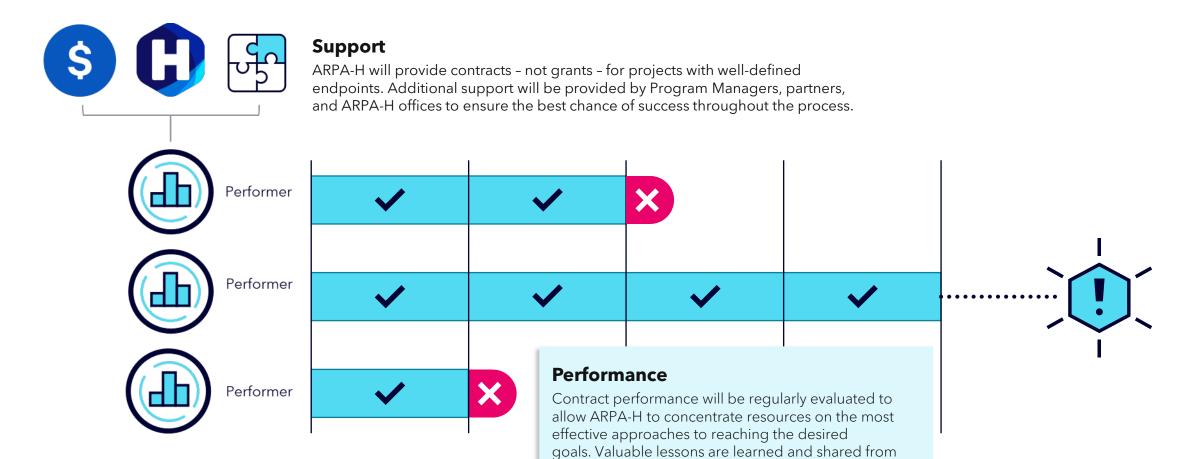
ARPA-H Model: Program Formation

Program Manager Challenge **Program Launch Performers Program Manager identifies** The challenge should NOT A Program Manager seeks – and Performers compete to carry a difficult health-related challenge be easily solvable through oversees - several groups of out their potential innovative that is ripe for solving. traditional activities. performers aiming to solve the solutions to the challenge same problem in unique ways.



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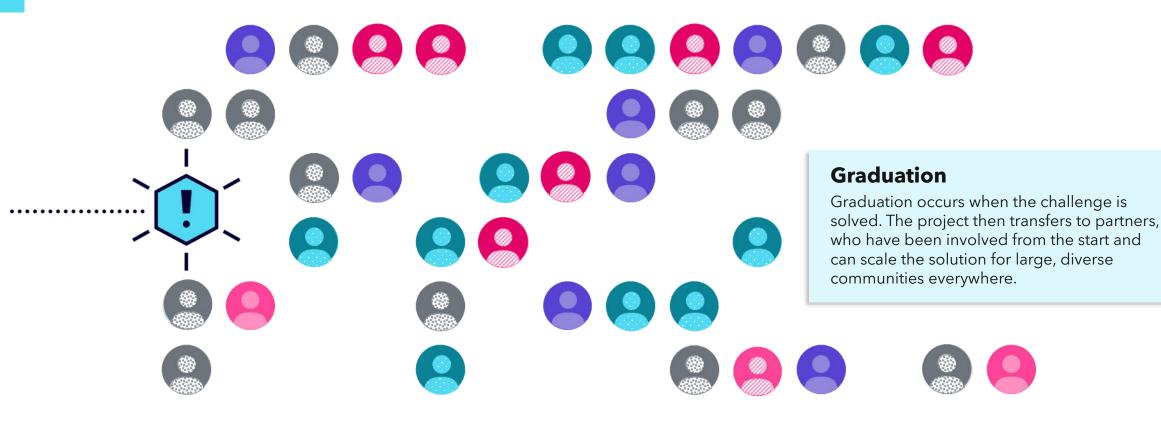
ARPA-H Model: Support and Evaluation



each project.

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ARPA-H Model: Transition





Industry is a key partner in the transition process.



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

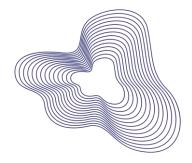


Transition/Outputs Survive in the Wild

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



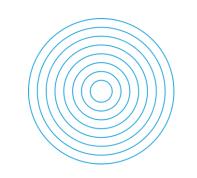
Initial Mission Focus Areas



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

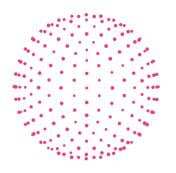
Address health challenges that include geography, distribution, manufacturing, data and information, and economies of scale to create programs that result in impactful, timely, and equitable solutions.



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.





Ways industry can work with us



Open BAA – calling for proposals to outline breakthrough research and technological advancements to improve health outcomes across patient populations, communities, diseases, and health conditions.



NITRO BAA - ARPA-H's first Program BAA seeks funding proposals to address current issues surrounding osteoarthritis treatment by developing new ways of helping the human body repair its own joints.



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



Site Selection - Hub & Spoke Health Innovation Network - ARPA-H seeks to establish sites in three geographic locations across the United States through the pursuit of a hub-and-spoke strategy. Check our website for opportunities to partner with ARPA-H.

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.



Engage Now arpa-h.gov | careers@arpa-h.gov



First Program Launch!

Novel Innovations for Tissue Regeneration in Osteoarthritis (NITRO)

Vision: To eradicate OA through targeted, regenerative therapeutics that will revolutionize the care algorithm, prevent pain, decrease the economic burden, and eliminate the need for repeat joint surgery.

Technology focus areas

- Needle-based and/or non-invasive bone regeneration
- Needle-based and/or non-invasive cartilage regeneration
- Replacement joints built from human cells

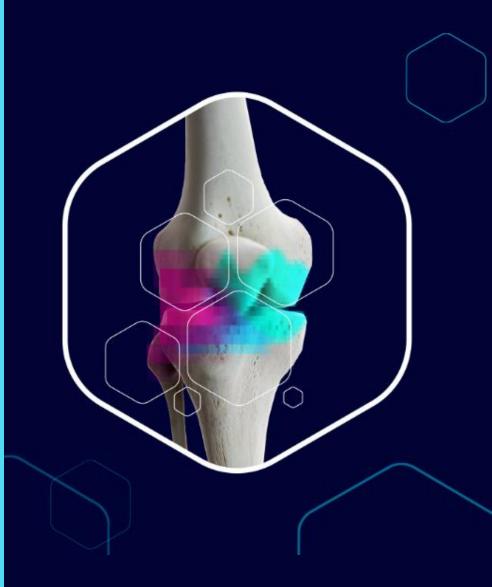
How to apply

- Submit abstract and, if invited, full proposal
- Visit <u>arpa-h.gov</u> for more information about NITRO and applying to the BAA or email: <u>NITRO@arpa-h.gov</u>

Important Dates

- A hybrid Proposers' Day for interested research teams is scheduled for **June 15, 2023**
- Program BAA will close on July 28, 2023, at 11:59 pm ET





What if we could make our joints heal themselves?







Alicia Eggert This Present Moment 2019 - 2020 Currently @ The Renwick Gallery Washington, DC