ARPA-H: The Mission

Advanced Research Projects Agency for Health (ARPA-H)

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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.”

— President Biden Remarks, March 18, 2022
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
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 decision-making.** 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.
ARPA-H Health Ecosystem

CUSTOMERS

Patient Groups
Healthcare Providers

PERFORMERS

Academia
Industry

STAKEHOLDERS

NIH
Federal Partners: FDA, CMS, HRSA, et al
Private Investors
NGOs

The Public

(and many others ...)

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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 forward-looking 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

The ARPA-H portfolio is:
1) a reflection of the PMs
2) dynamic, and
3) will – and should! – change frequently

PMs: 3-6 Years
Programs: 2-4 Years

PROGRAM MANAGERS
PM joins with their vision to advance health outcomes

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

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

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

Program Manager
Program Manager identifies a difficult health-related challenge that is ripe for solving.

Challenge
The challenge should NOT be easily solvable through traditional activities.

Program Launch
A Program Manager seeks – and oversees – several groups of performers aiming to solve the same problem in unique ways.

Performers
Performers compete to carry out their potential innovative solutions to the challenge.
ARPA-H Model: Support and Evaluation

Support
ARPA-H will provide contracts – not grants – for projects with well-defined endpoints. Additional support will be provided by Program Managers, partners, and ARPA-H offices to ensure the best chance of success throughout the process.

Performance
Contract performance will be regularly evaluated to allow ARPA-H to concentrate resources on the most effective approaches to reaching the desired goals. Valuable lessons are learned and shared from each project.
ARPA-H Model: Transition

Industry is a key partner in the transition process.

Graduation
Graduation occurs when the challenge is solved. The project then transfers to partners, who have been involved from the start and can scale the solution for large, diverse communities everywhere.
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

Connect with us
@ARPA_H @ARPA-H /ARPA-H
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 arpa-h.gov for more information about NITRO and applying to the BAA or email: NITRO@arpa-h.gov

**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?