ARPA-H: The Mission
The Advanced Research Projects Agency for Health

Susan Coller Monarez, Ph.D.
Acting Deputy Director, ARPA-H

Federation of Associations in Behavioral & Brain Sciences
December 5, 2022
Our Mission

Accelerate better health outcomes for everyone.
“ARPA-H will pursue ideas that break the mold on how we normally support fundamental research and commercial products in this country.”

“One idea 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
Our Slow Sputnik 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.
Imagine if...

- Cell therapies could be built and assembled on demand, readily re-programmed for each new disease target
- MRIs could be delivered in the comfort of your home
- A personalized cancer vaccine cost the same as a cup of coffee
- We could all realize a better health future.
ARPA-H Organization within HHS

ARPA-H At-a-glance

- $1B Initial budget to start
- Independent component of HHS within NIH, reporting directly to HHS Secretary
- No internal research labs; disease agnostic
- Program Manager driven ideas and decision-making
- Lean and nimble management structure
- High Risk/ High Consequence Research
The Program and Program Manager Flywheel

PM joins with their vision to advance health outcomes
ARPA-H Health Ecosystem

**Stakeholders**
- NIH ICs
- FDA
- CMS
- HRSA
- NGOs
- (and many others...)

**Customers**
- The Public
- Healthcare Providers
- Patient Groups

**Performers**
- Academia
- Industry
Program Lifecycle
From ideas to solutions in the real world

DESIGN PROGRAMS
- ARPA-Hard and well-defined problems in health
- Heilmeier Framework
- High risk/High consequence
- Stakeholder Insights

BUILD A PERFORMER TEAM
- Solicit Solutions from the community
- Find the best non-traditionals, 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

COMMERCIALIZATION & TRANSITION
- Assist company formation or licencing
- Provide mentorship, connections to customers, investors
- De-risk investments
**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.
THE POSITION

- Timebound (3 - 6 years)
- Competitive salary
- PMs diverse in geography, demographics, experience, and topic
- **Full business and technical team support** for day-to-day program management, market assessments, transition, budget, human-centered design, etc.
- **Resources and opportunity to change the future of health**
- **Responsibility to identify well-defined problems in health**, and assemble teams from industry, academics, and government to solve.

THE OPPORTUNITY

“My time as a DARPA PM was probably one of the most inspiring periods of my professional career. I cannot think of a more noble endeavor than to work as a PM for the newly created ARPA-H to solve the grand health challenges that society faces.”

Darryll J. Pines, Ph.D., NAE
Program Managers
What are the Phenotypes of these Rational Risk Takers?

Uncommon people with common traits

RECOGNIZED EXPERTISE
SERIOUS DRIVE
INSTATIABLE CURIOSITY
NO FEAR OF FAILURE
INTERDISCIPLINARY TRACK RECORD
TECHNICAL HONESTY

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 TINKERER
Intrinsic desire to build and experiment. 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.
## 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)?
To Define Success
Solutions are **NOT** research grants.

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…
Project Accelerator Transition Innovation Office (PATIO)

Increasing the odds - at each step - that solutions can “survive in the wild”

**PROGRAM LIFECYCLE**

**PROGRAM DESIGN**
Support PM 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**
- SBIR/STTR
- Transition partner/Third-party investment
- Ongoing mentorship
- Access to key customers and investors
PATIO Services Overview

What’s in the PM Toolkit

- Customer Discovery
- Entrepreneurship Education
- Mentors/Coaches
- MVPs to De-Risk
- Non-Dilutive Capital
- Venture-Backable Entrepreneurs
- Access to Venture Capital
- Early Technical and Business Hires
ARPA-H Associated Initiatives

Cancer Moonshot
Obama tasks Biden (VP) to launch effort to “end cancer as we know it” at last State of the Union

The Cures Act is signed into law. The Cancer Moonshot is appropriated ($300M for first year)

In the first 4 years:
- 2,000+ publications
- 49 clinical trials
- 30+ patent filings

Biden calls on Congress to fund ARPA-H during State of the Union

ARPA-H is appropriated with a budget of $1B over 3 years

New NCI Director Announced

New goals are set for the Cancer Moonshot 2.0

Inaugural ARPA-H Director announced at Cancer Moonshot event
# Cancer Moonshot and ARPA-H Comparison

<table>
<thead>
<tr>
<th>Mission</th>
<th>Reduce cancer death rate by 50% in 25 years</th>
<th>Accelerate better health outcomes for all</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focus area</td>
<td>Cancer</td>
<td>Disease-agnostic</td>
</tr>
<tr>
<td>Structure</td>
<td>Cross-agency efforts without dedicated dollars past 2023</td>
<td>Independent component of HHS within NIH, reporting directly to HHS Secretary</td>
</tr>
<tr>
<td>Funding</td>
<td>NIH-funding mechanisms</td>
<td>Flexible awarding mechanisms</td>
</tr>
<tr>
<td>Methodology</td>
<td>Peer-reviewed, methodical</td>
<td>Program Manager-inspired: high risk innovation</td>
</tr>
</tbody>
</table>
Cancer Moonshot
2022 Strategic Priorities

1. Close the screening gap
2. Address environmental exposure
3. Decrease impact of preventable cancers
4. Bring cutting edge research to patients
5. Support patients and caregivers
How Might ARPA-H Contribute to the Moonshot?

ARPA-H can appoint a Cancer Moonshot Champion to:

- **Identify** internal efforts across mission offices that utilize the whole of ARPA-H that are aligned to Cancer Moonshot
- **Engage** stakeholders on behalf of the government
- **Collaborate** with Cancer Moonshot leaders in OSTP, NIH, and across government

PMs can:

- **Leverage** infrastructure (e.g., data, networks) and implementation pathways
- **Translate** ongoing research efforts into capabilities for researchers or patients
- **Solve** problems prioritized in the Moonshot that can’t be solved otherwise

**Striking the right balance:**
Collaborating to seize the moment, while maintaining the flexibility for ideas and domains beyond cancer.
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
• AI, 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

Moonshot Priority: #4 Bring cutting edge research to patients
ARPA-H Call to Action

Apply - 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

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

Engage - We are actively engaging research, patient, and stakeholder, communities; we want to hear from you!

inquiries@arpa-h.gov

@ARPA_H | ARPA-H | @ARPA-H
Reproducing Content, Logos, and Graphics

Information in this presentation can be freely shared, downloaded, and reproduced. Content reproduced without changes should acknowledge ARPA-H as the source.

There are a few exceptions.

- You may encounter documents that were sponsored along with private companies and other organizations. Accordingly, other parties may retain all rights to publish or reproduce these documents or to allow others to do so.
- ARPA-H logos should not be used without explicit review and approval by ARPA-H.
- Some graphics have been licensed by a third party and are restricted in their use.
- Generally, copyrighted materials will include a copyright statement. If you have questions, please contact web@arpa-h.gov.

As a government entity, ARPA-H does not hold rights to the content it produces, and does not sign indemnity or hold harmless statements, release from copyright infringement, or similar documents.

Editing Content
ARPA-H logos must be removed from edited content. ARPA-H content must not be used to imply endorsement of any companies, organizations, commercial products, processes, or services; or to recommend specific medical advice, treatments, or referrals.

Additional Questions
If you have additional questions on ARPA-H copyright, contact web@arpa-h.gov.