



Proactive Health Office (PHO) Innovative Solutions Opening (ISO) Virtual Proposers' Day

April 9, 2024

Approved for Public Release: Distribution Unlimited

Proactive Health Office Innovative Solutions Openings Virtual Proposers' Day Agenda (ET)

Time	Slot	Speaker
2:00pm	Welcome	Wade Shen, PHO director
2:05-2:15pm	ARPA-H 101	Renee Wegrzyn, ARPA-H director
2:15-2:35pm	Proactive Health Office	Wade Shen, PHO director
2:35-2:45pm	Acquisition details: PHO ISO	Caitlin Burns, ARPA-H agreements officer
2:45-2:55pm	Q&A	Caitlin Burns, Wade Shen
2:55-3:00pm	Close	Wade Shen

ARPA-H: The Mission

Advanced Research Projects Agency for Health (ARPA-H)

Renee Wegrzyn, Director

April 9, 2024

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Mission

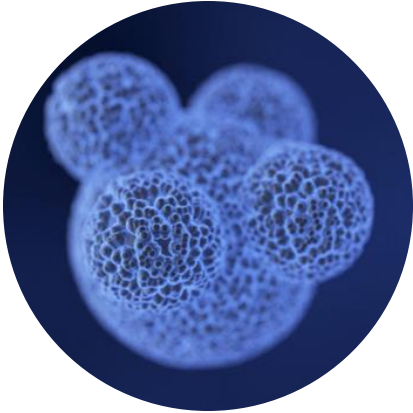
Accelerate better health outcomes for everyone.



ARPA-H Organization within HHS

- ARPA-H is a **funding agency**
- **Independent** component of HHS within NIH; not an Institute
- No internal research labs; **disease agnostic**
- Generally **fund outcome-based contracts**, not grants; accelerated award timelines
- Unique **FDA reimbursement authority**
- **Appropriations**, budget independent from NIH

FY 2022	FY 2023	FY 2024	FY 2025
\$1B	\$1.5B	\$1.5B	Request: \$1.5B



HOW?

We are a unique funding agency by design

Function like a Business – Quickly, Nimbly, and Decisively.

**Authorities
Contracts
Big Bets**



WHO?

Problem-focused Program Managers drive innovation

Facilitating the Future

**Change Agents
Our Performers
Our Customers**



WHAT?

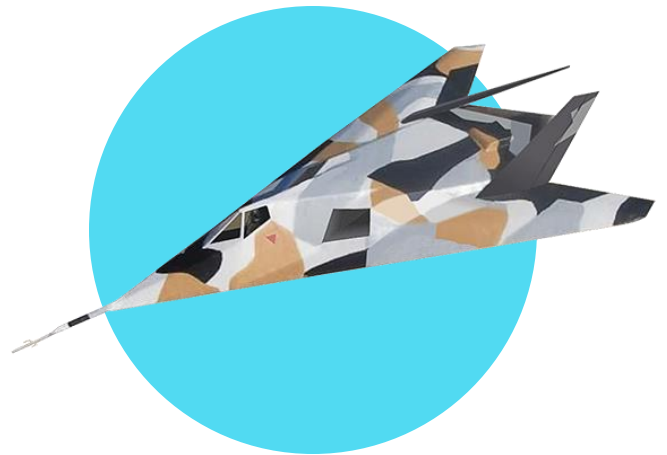
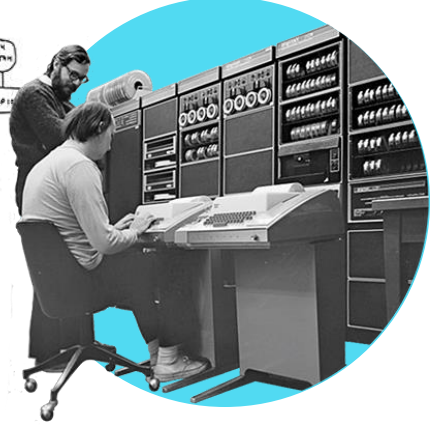
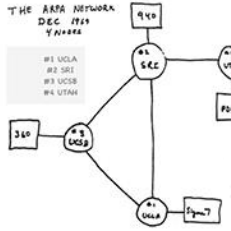
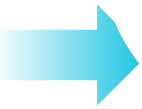
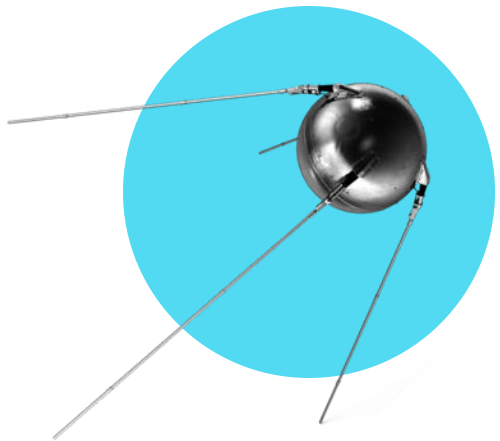
We are seeking radical change

Moonshots for Health

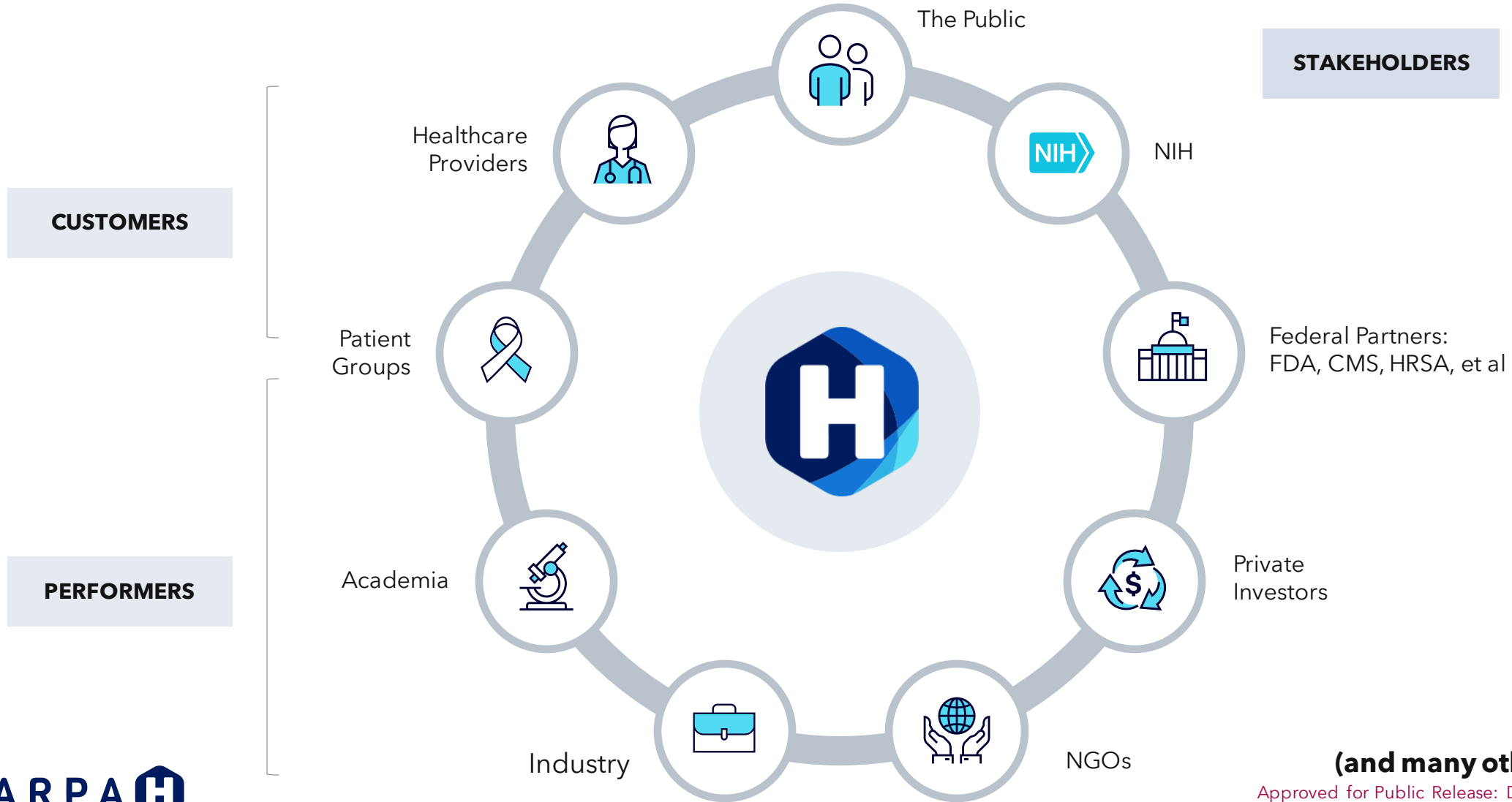
**Risks
Urgency
Real-world Impact**



The Promise of the ARPA-H Model



ARPA-H Accelerates the Entire Health Ecosystem



ARPA-(H)eilmeier Questions

Creating programs with well-defined problems

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? What Health Outcomes are we accelerating?

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

6 How long will the program take?

7 How much will the program cost?

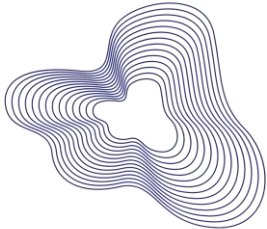
8 What are our mid-term and final exams to check for success?

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 build trust and prevent that from happening)?

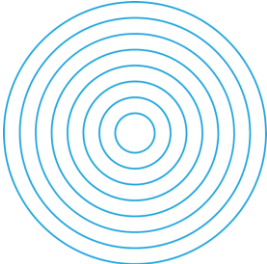
Mission Focus Areas and Ideation

Further ARPA-H investment in these areas will generate **asymmetrical benefits** to the health ecosystem



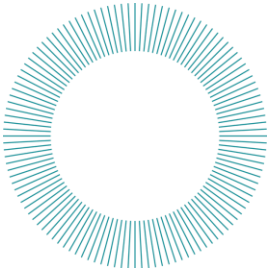
Health Science Futures

Expanding what's technically possible



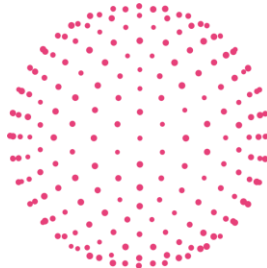
Scalable Solutions

Reaching everyone quickly



Proactive Health

Keeping people from being patients



Resilient Systems

Building integrated healthcare systems



Project Accelerator Transition Innovation

Ensuring programs survive in the wild



Ideation at ARPA-H

- **Programs:** Initiated by Program Managers to address major health challenges.
- **Projects:** Sourced from community via the Innovative Solutions Openings (ISOs), enabling grassroots innovation.



Become a Program Manager

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



ARPA-H Timeline



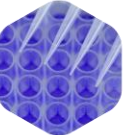

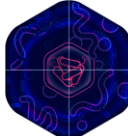

ARPA-H appropriations passed in omnibus

2023

2024

DEC MAR MAY JUN JUL AUG SEP OCT NOV DEC JAN FEB MAR


"Open for Business" - ARPA-H launches its first Agency-wide Open BAA

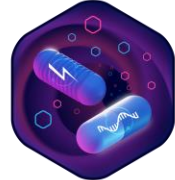


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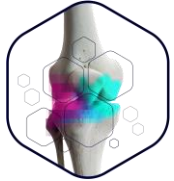
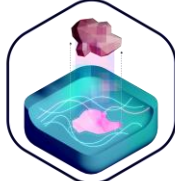




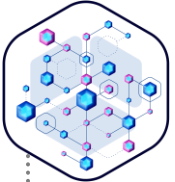
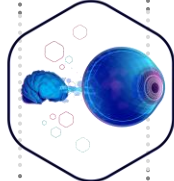

CUREIT

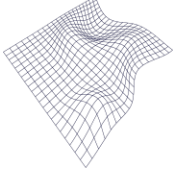

9 SBIRs


ARPANET-H


Women's Health


REO 	PIC-OCT 	MATRIX 
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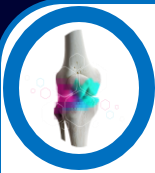
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BDF


ACTR




ARPA-H's Investment Portfolio Snapshot: What if...?



NITRO

What if we could make our joints heal themselves?



REACT

What if your body could make its own medicine?



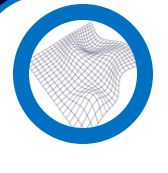
DIGIHEALS

What if we could strengthen the nation's digital health infrastructure to protect against cyberattacks?



APEX

What if we could eliminate viruses as current and future health burdens?



BDF

What if next generation tools can synthesize and speed the use of health research data?



PARADIGM

What if we could deliver advanced hospital-level care to every rural county in America?



SPIKEs

What if programmable bacteria could be directed to kill cancer inside the body?



DARTS

What if we could identify antibiotic-resistant bacteria in minutes?



MATRIX

What if we could immediately determine if FDA-approved drugs could treat rare and/or untreatable diseases?

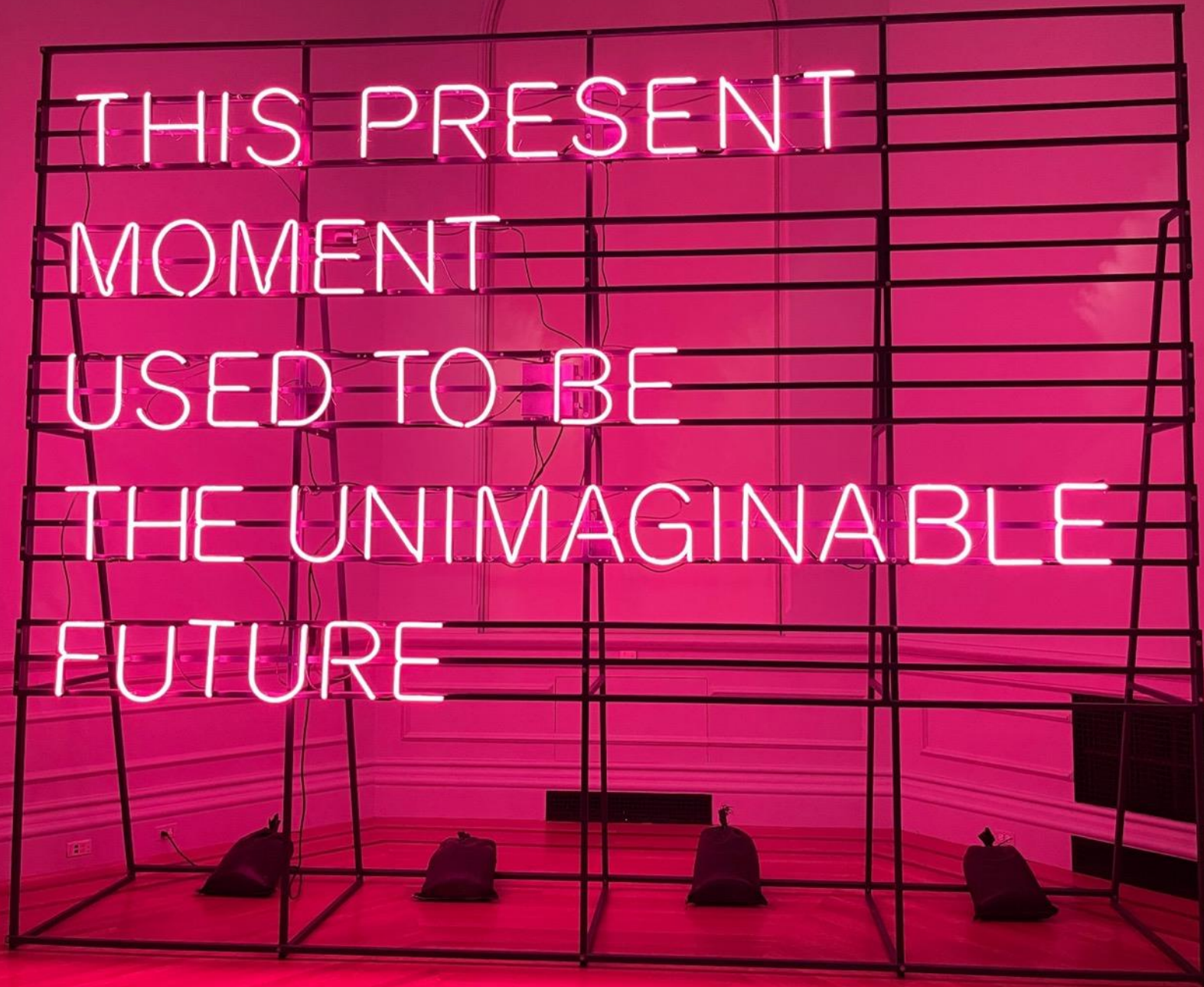


ADAPT

What if we could adapt cancer treatments as tumors mutate and change?



@ARPA_H



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

Proactive Health Office

Wade Shen, Director

Proactive Health Objectives

Prevent, detect and mitigate the effects of adverse mental & physical illness

	Prevent	Diagnose	Delay/mitigate
Novel core approaches			Proactive treatment for cancer metastasis
Innovations that improve individual adoption	Low side-effect vaccine	Low-cost, high-accuracy blood-based screening for colon cancer	
Health systems innovations that improve access and availability	Personalized and interactive public health education		

Cross-cutting PHO program accelerants

- T&E/Data infrastructure for long-term outcome tracking
- Accelerated capacity to develop novel detection, prevention and illness-delaying interventions

ISO projects vs. programs

	Programs	ISO Projects
Scope	Address multiple core tech, adoption and access challenges	Address few but focused challenges
End-of-effort goals	Demonstrate new or radically improved capabilities that create compelling real-world evidence of effectiveness, adoptability and scalability	Demonstrate possible solutions to specific challenges; may still require additional R&D
Duration	3-5 years	1-3 years



Target for ISO Applications

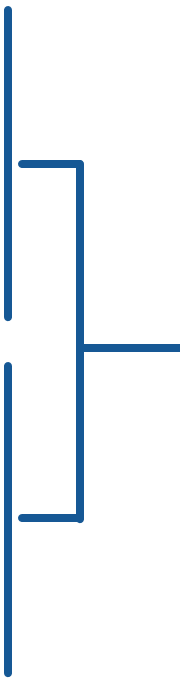
Example prevention project: Effective, low-cost training of lay mental health workers

Problem:

- 1. Preventative treatment for depression and anxiety is estimated to be able to prevent 22-38% of depressive episodes [1]
- 2. Only 1.2M trained mental health workers to treat 48M Americans at risk of depression and anxiety

Opportunity:

- 1. Peer support can reduce depression better than care-as-usual and on par with cognitive behavioral therapy, but training and development is time intensive [2];
- 2. Automated and personalized curriculum delivery shown to improve educational outcomes 2-2.5x [3]



Example ISO project
Personalized curriculum to train lay health workers and peers that is 95% effective for those without access to treatment. Training successful without need for expert trainers.

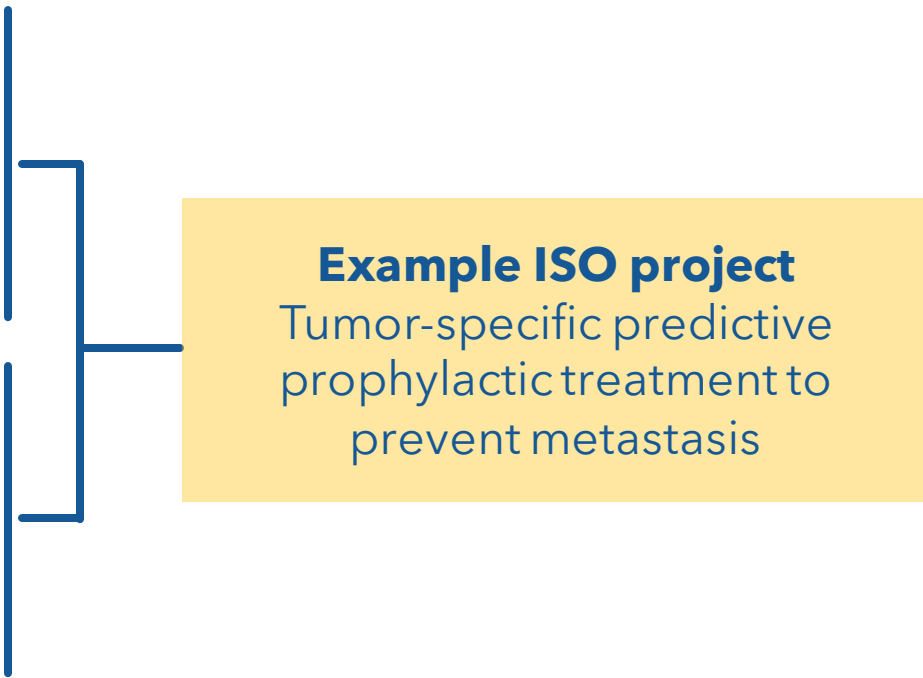
Examples of delay/mitigation project: Prophylactic treatment of metastatic cancer

Problem:

Cancer continues to be the second leading cause of death [1] and 67-90% of cancer deaths still arise from metastatic disease [2] despite curative and secondary prevention methods

Opportunity:

- 1. Large-scale aggregation of cancer pathology samples
- 2. More detailed genetic/proteomic characterization of tumor and microenvironment
- 3. AI models of cancer evolution



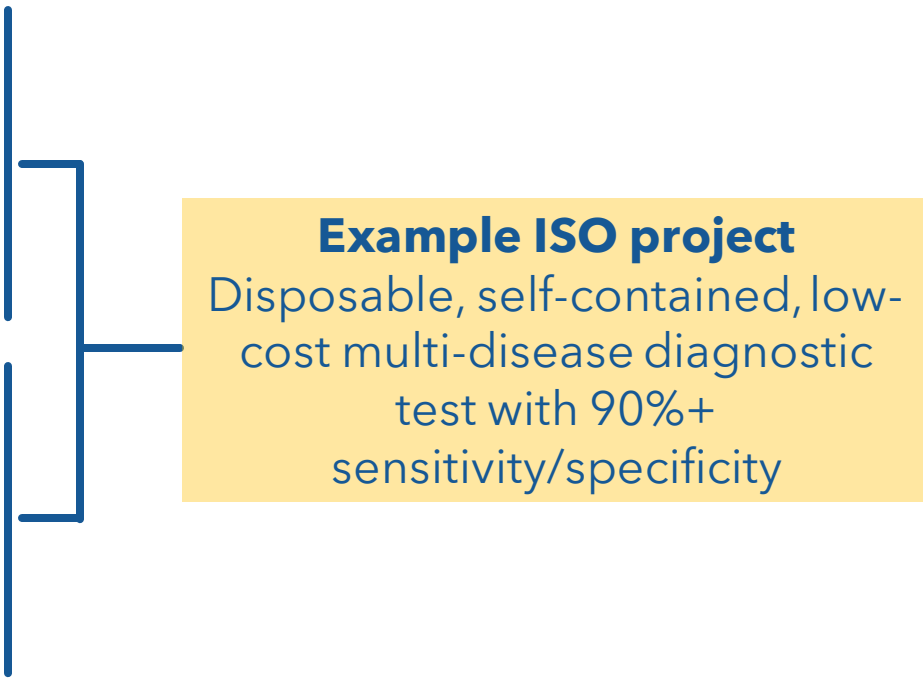
Example early diagnostics project: Disposable, low-cost multi-disease diagnostic tests

Problem:

- 1. Infectious disease causes 10M+ infections, 0.5M+ hospitalizations and more than 100,000 deaths each year (includes 50K+ deaths attributed to COVID-19 in 2023) [1]
- 2. Testing for most infectious diseases costly, slow and limited to clinics and hospitals
- 3. Testing at home limited by disease coverage and accuracy

Opportunity:

- 1. Early diagnostics of flu (as an example) has been shown to reduce infection rates by up to 32% [2]
- 2. Novel home-user friendly/accurate assays
- 3. Multi-pathogen assays getting cheaper [3]



[1] <https://www.cdc.gov/nchs/fastats/infectious-disease.htm>
[2] Neshler L, Tsaban G, Dreiherr J, et al. The impact of incorporating early rapid influenza diagnosis on hospital occupancy and hospital acquired influenza. *Infection Control & Hospital Epidemiology*. 2019;40(8):897-903. doi:10.1017/ice.2019.159
[3] <https://www.nature.com/articles/d41586-024-00854-7> isothermal multi-pathogen tests for at home use

Examples of potential cross-cutting PHO projects

	Cross-cutting problems	Opportunities	Example ISO projects
Improved capabilities and capacities	No ability to pay for long-term health outcomes	AI-driven forecasting; novel causal inference methods from observational data	AI-forecasting for long-term costs associated with preventative interventions
	High-cost and long development times for prophylactic therapies	Large repositories of proteins and chemicals with conformational structure; Novel chemical and biological models that predict form and function	Data-driven ADME-Tox for novel drugs
Innovative test, evaluation and data resources	High-cost, high-latency trial design for preventative care (especially outside the medical system)	Proliferation of life/health data; tracking and remote follow-up for patients	Novel high-throughput trial design that assess self-administered and medically delivered preventative care
	Lack of ability to longitudinally measure outcomes of preventative care	Biobanks covering large populations; large-scale causal discovery of novel biomarkers	Modeling capability for EHR + biomarker + demographic/SDoH data for long-term outcomes

Acquisition Details

PHO Innovative Solutions Opening

Caitlin Burns

Business Innovation Division

Common Terms & Definitions

- ISO Types
 - Program-Specific ISOs are issued to solicit proposals for a specific program.
 - No common statement of work
 - Seeks proposals that address a common problem or issue
 - Non-program Specific ISO are issued by MOs within the Agency or by the Agency itself and allows proposers to submit proposals that support the mission of the MO or the broader Agency mission.
- Conforming/Non-conforming
 - Submissions that comply with the requirements of the ISO will be considered conforming and will be evaluated.
 - Submissions that do not comply with ISO requirements will be considered non-conforming.
- Review Team: comprised of the PM, delegate PM (as applicable), SMEs (as applicable), Government Reviewers, the Senior Review Official (SRO) and delegate SRO (as applicable)
- Selectable/Not Selectable
 - A proposal is considered Selectable if the positive aspects of the overall proposal outweigh its negative aspects, and there are no deficiencies or accumulated weaknesses that require extensive negotiations and/or a resubmitted of a full proposal.
 - A proposal is considered Not Selectable if the positive aspects of the overall proposal do not outweigh its negative aspects, and there are deficiencies or accumulated weaknesses that require extensive negotiations and/or a resubmitted proposal.

PHO ISO Module Announcement Basics

Notable Dates

- ISO release date: 03/14/2024
- Virtual Proposers' Day: 04/09/2024
- Questions & Answers (Q&A) due date: Up to 6 months after Release Date
- Solution Summary Due: 03/03/2025
- Proposal due date: 05/06/2025

Award Types

- Other Transactions
- Cooperative Agreements

Eligibility

- Foreign Entities: Yes, preference given to those conducting funded work performed in the US
- FFRDCs: Not eligible in any capacity (prime or sub)
- Current internal professional support contractors: Not eligible

The ISO posted to SAM.gov is always the final authority

Award Overview

Other Transactions

- A contracting instrument with characteristics similar to those within commercial industry
- Encourage flexible, quicker, and cost-effective project design and execution when compared to traditional Gov't contracts
- Intended to strengthen the Public Health Industrial Base
- Provide ARPA-H access to state-of-the-art technology innovations/solutions
- Not subject to all acquisition laws and regulations
- A sample OT will be added to the ARPA-H website

Cooperative Agreements

- A federal financial assistance instrument (different than grants)
- Substantial ARPA-H involvement expected
- Involves collaboration between ARPA-H and the awardee during project performance is necessary
- Funding is intended for high-priority research areas for public purposes (not for procurements of goods or services)



Award Types - Other Transactions (OTs)

What are OTs?

- ARPA-H has authority to award OTs when "*use of such authority is essential to promoting the success of the project*"
- OTs are Agreements (e.g., mutual assent, expressed by a valid offer and acceptance; adequate consideration; capacity; and legality)
- OTs reflect commercial contracting rather than traditional FAR procurement contracts

OTs are collaborative

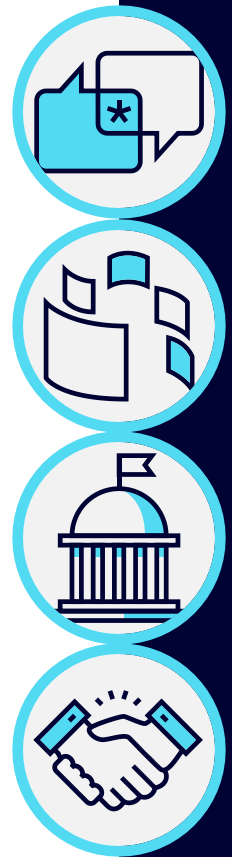
- Increased collaboration and partnership, leading to more effective use of resources and knowledge sharing.
- Free-flowing negotiations and less restrictive than FAR based procurements.



Other Transactions (OTs)

- **Pros:**

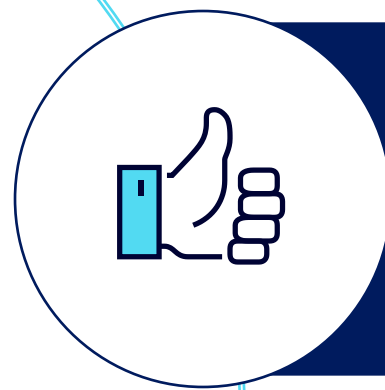
- Many laws/regulations do not apply
 - Competition in Contracting Act; Bayh-Dole; 45 CFR 75; FAR/HHSAR; Cost Accounting Standards; Bid Protests, etc.
- Invokes commercial practices, allowing for negotiating terms and conditions
 - May negotiate intellectual property (IP), payments, etc.
- Streamlined award process



- **Cons:**

- Lack the guardrails performers might desire under financial assistance or FAR contracts
 - Requires careful negotiation by knowledgeable parties
 - Can take longer to negotiate

Cooperative Agreements



Advantages

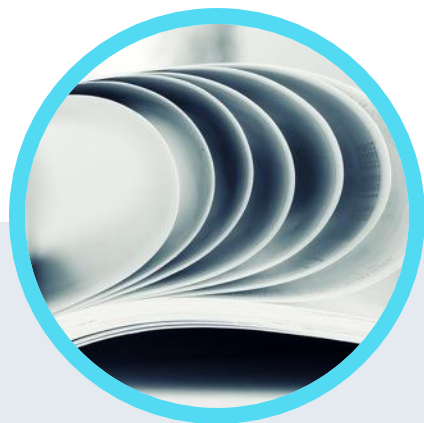
- Academic institutions and non-profits are familiar and comfortable with cooperative agreements (most have business practices and systems already set-up)
- May permit flexibilities including allowing up to 90-day pre-award cost, carryover of unobligated (unexpended) funds from one budget period to the next, and initiation by the recipient of a one-time extension of the PoP by up to 12 months
- Rebudgeting among direct cost categories where the transfer of funds does not exceed 10% or more of total costs of the most recently approved award
- Does not require HHS leadership pre-award approval



Disadvantages

- Mainly geared towards academic institutions (colleges and universities) and intended for early stage/basic research
- Not appropriate for acquiring prototypes - deliverables are generally reports only
- No exceptions to Bayh-Dole Act (Intellectual Property) means less flexibility
- Processes based on regulations/policies rather than negotiations
- Does not allow for the payment of profit or fee (exception under HHS policy allows for the profit/fee on SBIR/STTR grants)

Process Overview



Proposers' Day

- Proposers' Day is **NOT** mandatory to attend to submit a proposal
- Material presented today will be made available to the public via the ARPA-H website
- The PHO ISO is the official solicitation and therefore should be used as the official document to develop your proposals



Solution Summary Submission

- Submission IS mandatory
- **MUST** use Appendix A template provided
- Should include all sections noted in the template
- Submitted via the ARPA-H Solutions Website



Proposals

- Will be encouraged/discouraged from solution summary
- Requested 45 days from encouraged to submission
- Submitted via [ARPA-H Solutions](#)



Evaluation and Selection

- The Government will review each conforming proposal against criterion in descending order of importance.
- Selection for potential award will be made as outlined in the ISO

Evaluation Criteria

1

Overall Scientific and Technical Merit

- Innovative, feasible, achievable, and complete
- An outcome that achieves the expected goals
- Technical risk(s) identification with a feasible mitigation strategy
- Intellectual Property (IP) rights structure; impact to Gov's ability to transition

2

Proposers' Capabilities and/or Related Experience

- Team expertise and experience
- Experience in managing similar efforts

3

Potential Contribution and Relevance to the ARPA-H Mission

- Future application, including unmet needs within biomedicine and to improve health outcomes
- Potential for interdisciplinary approach

Evaluation Criteria, Stage 2

4

Price and Value Analysis/Cost Realism/Reasonableness

- Price Reasonableness - Ensure the overall price is fair and reasonable (e.g., not too high no too low)
- Do prices reflect the technical goals and objectives of the solicitation and the proposed scope of work
- Value Analysis - what is the value of the research in comparison to the proposed price

Final Guidance

Monitor SAM.gov

- Any/all changes to the ISO will be made via formal amendments and posted online at [SAM.gov](https://sam.gov)
 - No information discussed at Proposers' Day shall be construed as modifying the terms and conditions of the ISO published

Conform to all Requirements

- Thoroughly read the ISO
- Non-conforming proposals **will not** be evaluated or considered for award



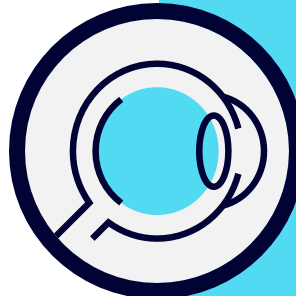
Reminders

- Use the Bundle of Attachments to develop your proposal submissions
- Read the ISO in total before you develop your proposal



Dates and Deadlines

- Solution Summaries Due Date: March 3, 2025
 - Submit to [ARPA-H Solutions](#)
- Proposal submitted by ISO closing to [ARPA-H Solutions](#)



Questions

- Submit questions to [ARPA-H Solutions](#)

Q&A

Caitlin Burns, Wade Shen

Ask a question



<https://solutions.arpa-h.gov/Ask-A-Question>

Please note, questions not answered today will be addressed + maintained in a frequently asked questions document available on the ARPA-H website

Thank you

ARPA 