ARPA H

Open BAA Proposers' Day

Director's Office

April 4, 2023
Virtual Presentation

Approved for Public Release: Distribution Unlimited

Agenda

Eastern Standard Time

10:30 am – 11:00 am	**ZOOM Line Opens for Registered Participants**
11:00 am – 12:00 pm	**Government Briefings** • **Agency Vision** – Dr. Renee Wegrzyn • **Open BAA Rationale and Mission Office Briefing** – Dr. Amy Jenkins and Dr. Jennifer Roberts • **Acquisition Details and Next Steps** – Mr. Benjamin Bryant
12:00 pm – 12:30 pm	**Break and Submit Questions**
12:30 pm – 1:00 pm	**Live Response to Questions**

Agency Vision

Dr. Renee Wegrzyn

ARPA-H Director

ARPA H

Mission

Accelerate better health outcomes for everyone.

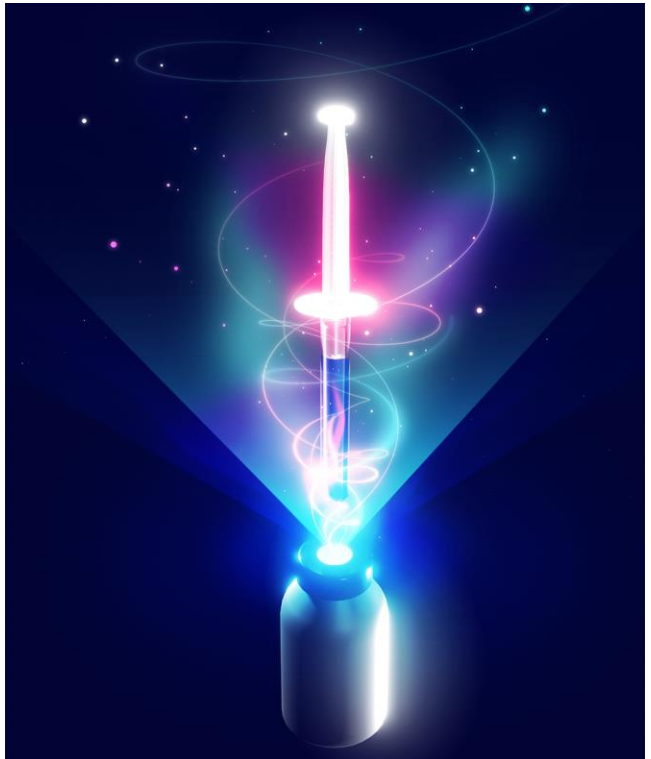
President Biden's Vision

"ARPA-H will pursue ideas that break the mold on how we normally support fundamental research and commercial products in this country."

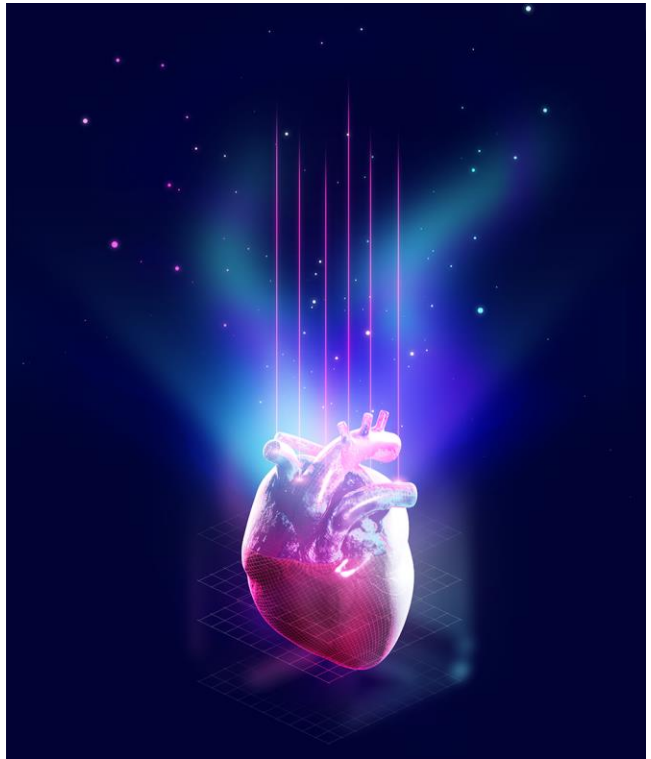
"Ideas so audacious that people say they just might work only if, only if, we could try. Well, we're about to try in a big way."

– President Biden Remarks, March 18, 2022

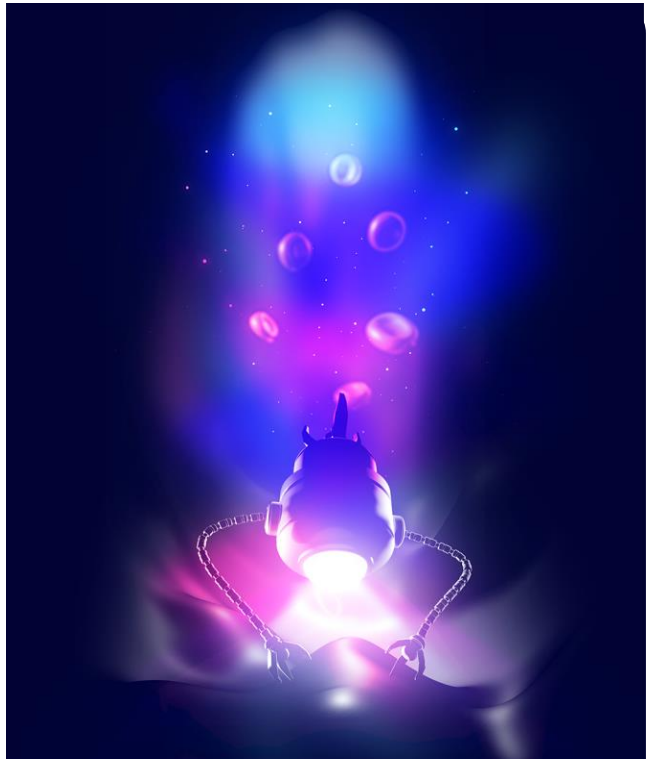
Imagine if...



A personalized cancer vaccine cost as little as a cup of coffee

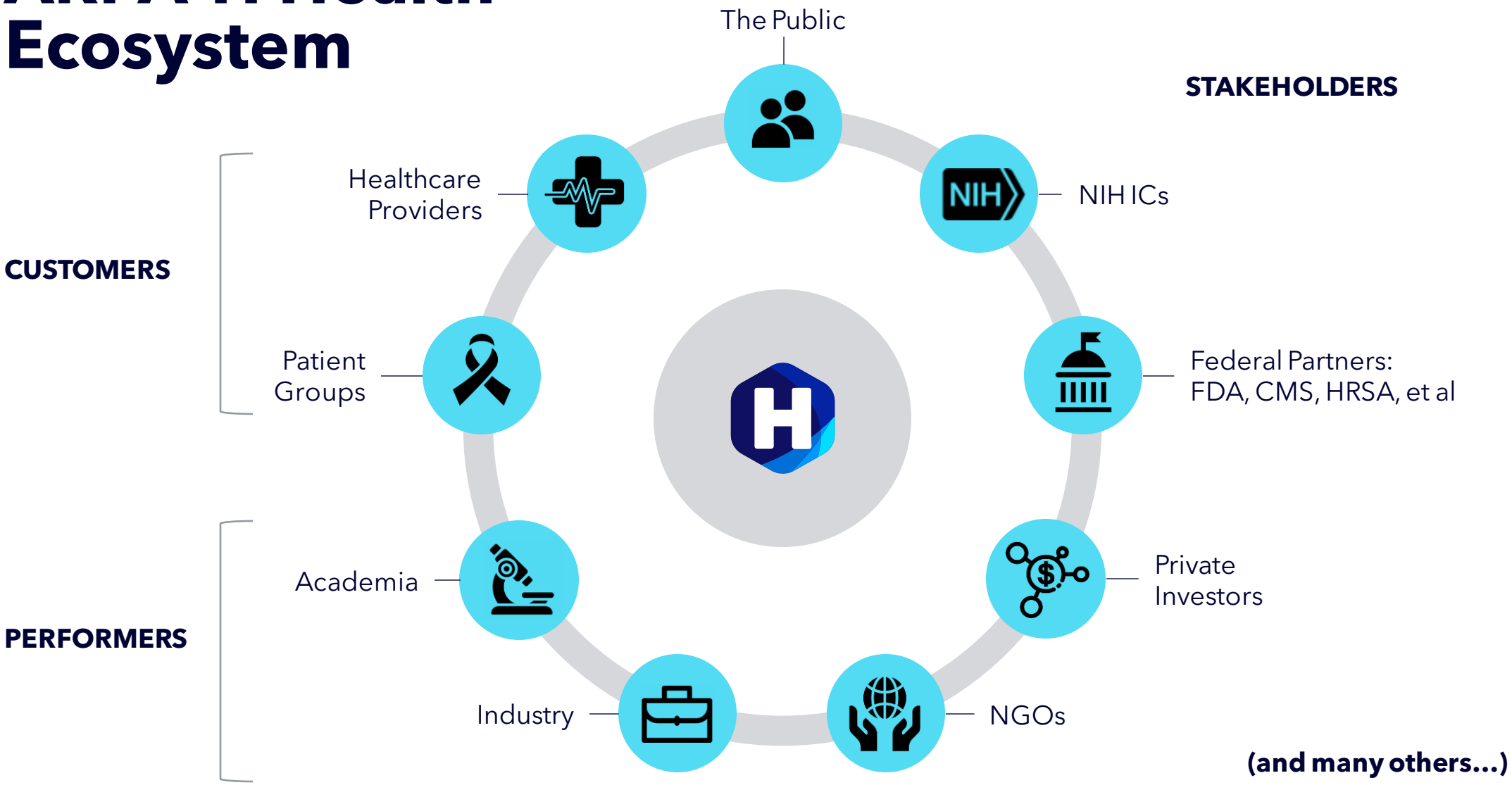


A damaged organ could be replaced by one 3D bioprinted in a lab



A surgical nanorobot could be delivered by a pill

ARPA-H Health Ecosystem



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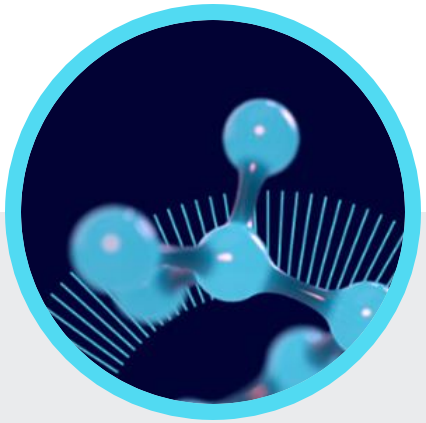
ARPA-H is Open for Business!



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 by 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.

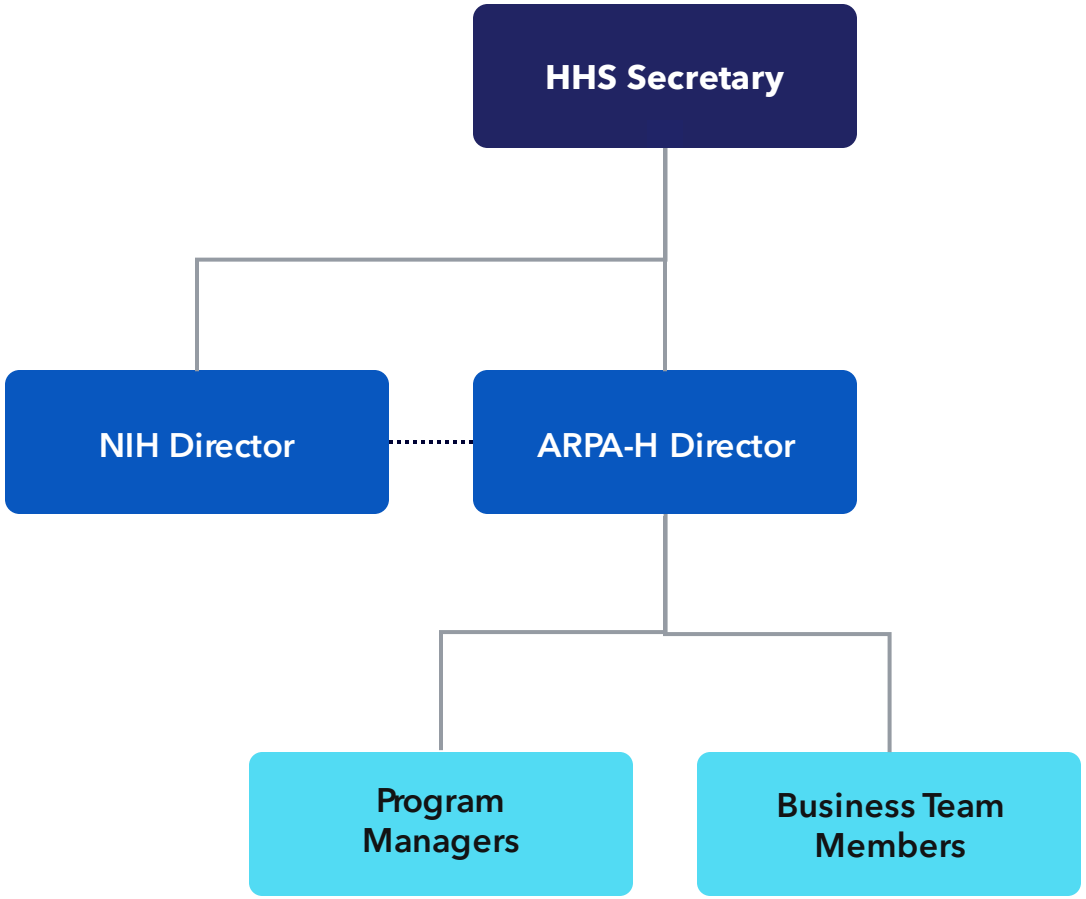
Request for Proposals | ARPA-H & SAM.gov

ARPA-H Dash

The ARPA-H Dash to Accelerate Health Outcomes, or "ARPA-H Dash," has launched 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

ARPA-H Organization within HHS



ARPA-H Key Features and Authorities

- ARPA-H is a Federal R&D Funding Agency.
- Congress has provided $2.5B to start; funding independent of NIH.
- Independent component 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.

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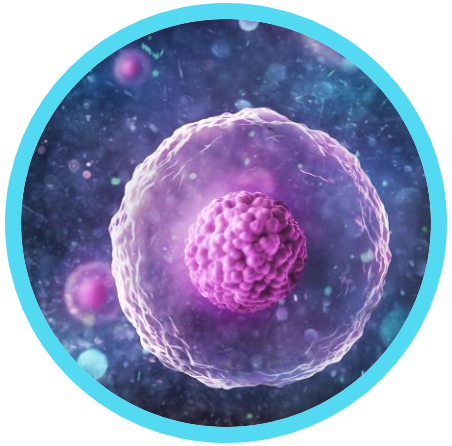
Organizational Attributes



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 forward-looking science and technology.

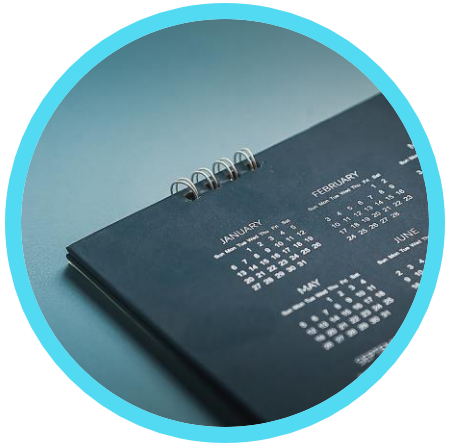
Autonomy

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, 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.

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-traditional, industry, and academics to solve.
- Build new coalitions.

Execute and Measure

- Active program management against metrics; PM = CEO.
- Stakeholder engagement throughout to ensure transition.
- Pivot resources when needed.

Learn and Grow

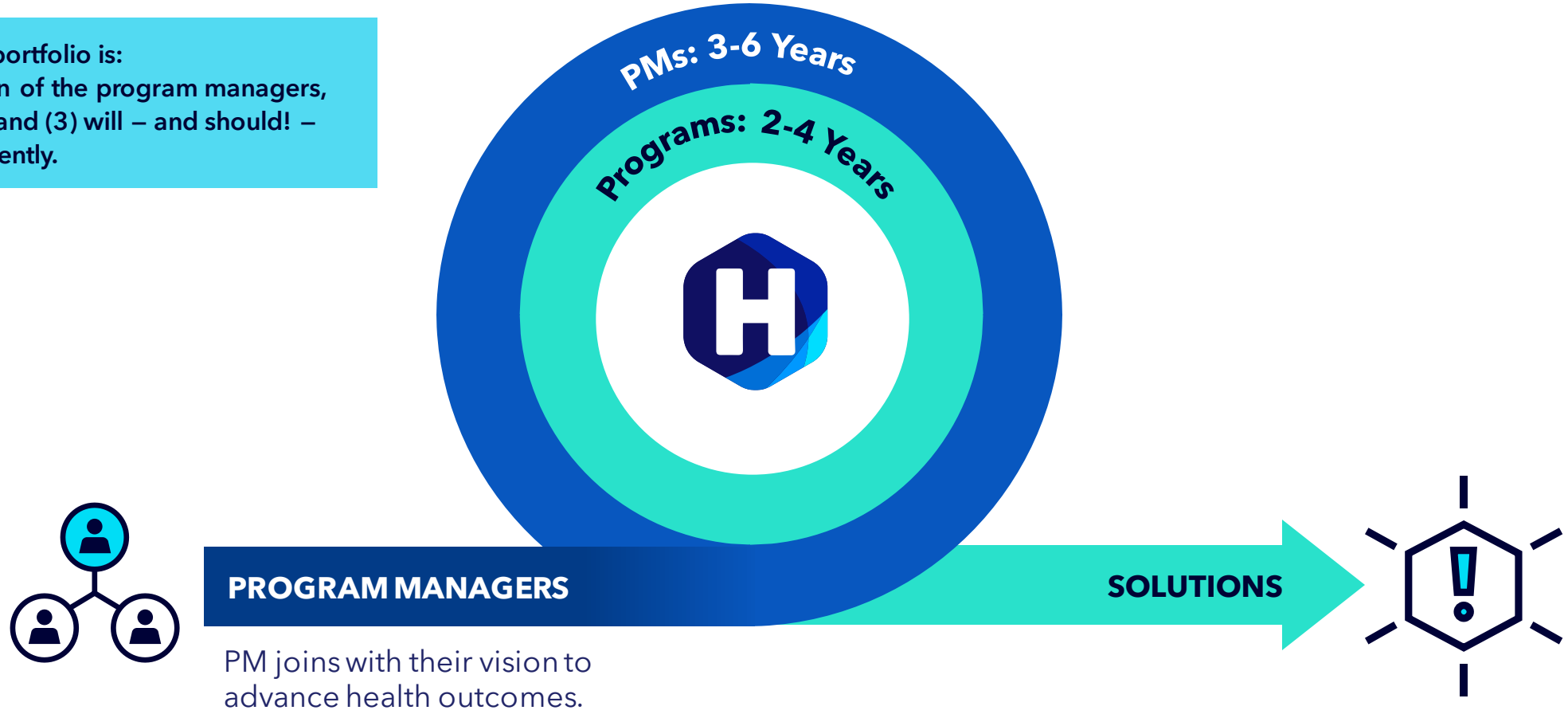
- Capture and share insights.
- Technical honesty.
- Advance the state of the art; 10x+ improvement, no incremental change.

Commercialize and Transition

- Assist company formation or licencing.
- Provide mentorship, connections to customers, investors.
- De-risk investments.

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.



Mission Office Overview

Dr. Amy Jenkins
Director, Health Science Futures Office

Dr. Jennifer Roberts
Director, Resilient Systems Office

ARPA H

Open BAA Rationale

Accelerate better health outcomes for everyone.

Opportunity to pursue novel ideas that are not currently covered by a program.

Rolling submissions for 1 year.

Revolutionary ideas required.

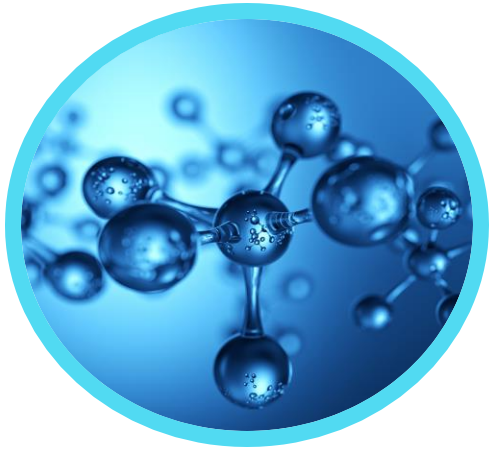
Scope of Open BAA Proposals

Proposal Scope

- Proof-of-concept to commercial viability
- Real-world evaluations and evidence generation
- All encompassing solutions and disease agnostic approaches are encouraged

Proposal Requirements

- Projects should be scoped appropriately to achieve the technical goals of the proposal
- Rigorous technical approach and cost realism



Teaming and Collaboration

- Bring together disparate technical backgrounds to meet goals.
- Potential to provide end-to-end approaches (e.g., discovery through production into clinical evaluation with a team of collaborators).

What is Revolutionary?

- **Proposals should describe an approach that is revolutionary and not evolutionary.**
- **What qualifies as "Revolutionary" can be quite subjective.**
- **The following are a few archetypes of ARPA efforts:**

Reframing

Reframes an existing problem so that rapid progress can be made.

- Leverages insights from a different field.
- Introduces a novel diagnostic device, sensor, or material to accelerate progress.
- Recasts a traditional problem statement, to reveal technical whitespace and/or challenge traditional assumptions.

Scaling

Qualitative changes in capabilities and society.

- Improving the speed, size, power, and resolution of a device ten-fold.
- Repackaging a capability so it can move from an academic medical center into someone's home.

Complexity

Engineering to assemble disparate components into a complex system that has synergistic functionality.

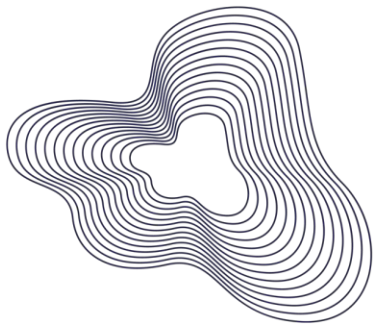
- Integration of disparate components to create a whole that is revolutionary compared to the sum of the parts.

What is Not Appropriate?

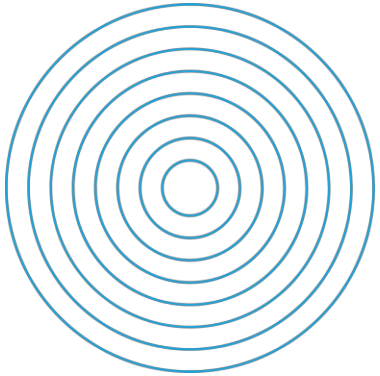
Proposals that are specifically excluded (Part II.I in BAA, pg. 4):

- ✕ Represent an evolutionary or incremental advance in the current state of the art.
- ✕ Direct towards policy changes.
- ✕ Fund specific product development (e.g., drug X that targets disease Y in a clinical study).
- ✕ Traditional education and training.
- ✕ Center coordination.
- ✕ Construction of physical infrastructure.

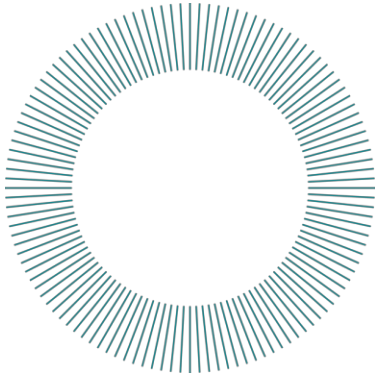
Initial Focus Areas



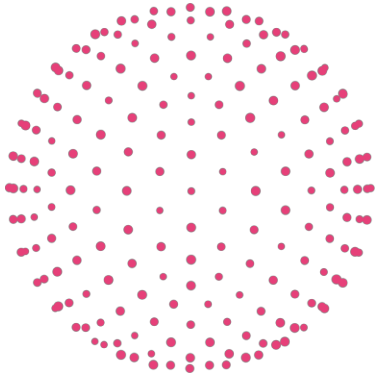
Health Science Futures



Scalable Solutions



Proactive Health



Resilient Systems

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).

Focus Areas

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.

Examples include:

- 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.

Focus Areas

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.***

Examples include:

- 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.

Focus Areas

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.

Examples include:

- 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.

Focus Areas

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.

Examples include:

- 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.

Acquisition Details

Mr. Benjamin Bryant

ARPA H

Agency-wide Open BAA Basics

Why an Agency-wide Open BAA?

- BAAs advance state-of-the-art and can increase knowledge and understanding of ARPA-H's goals.
- BAAs are typically a better fit for R&D over other award mechanisms:
  - Allow for varying technical/scientific approaches
  - Provide more input into the format, create an open dialogue between the Government and interested entities, and may lead to faster source selection.
  - *Prioritizes technical over cost.*
- BAAs are a comprehensive solicitation vehicle.
  - Please read the BAA closely as answers to most questions are there.

Agency-wide Open BAA Basics

Award Types

- Will choose award type based on best fit for project
- Awards will be Cooperative Agreements, Other Transactions, and Procurement Contracts.
- Will not award grants.

Award Timeline

- Ideal* is 90 days from receipt of full proposal to award but dependent on ARPA-H resources, award type, negotiations, etc.

Award Funding

- There is no funding limit for individual awards, no ceiling or award range for individual awards, or an overall ceiling for the BAA.

**could shift due to bandwidth*

Award Types – Cooperative Agreements

Financial Assistance

- Type of financial assistance mechanism used by the federal government to support collaboration and partnership between the government and a non-federal entity.
- Principal purpose is to transfer a thing of value to a recipient to carry out a public purpose of support or stimulation.

Substantial Involvement

- Unlike grants, cooperative agreements involve substantial involvement from ARPA-H, which may provide ongoing guidance and oversight throughout the project.

Benefits

- Parties work together to achieve a specific set of objectives or outcomes, with ARPA-H providing funding and technical assistance.
- Greater flexibility and discretion in project design and implementation, allowing for more innovative and customized solutions to complex problems.
- Enhanced accountability and transparency, as both parties are responsible for achieving the agreed-upon outcomes and reporting on progress and results.

Award Types – Other Transactions (OT)

OTs are agreements (not *FAR procurement contracts)*

- Mutual assent, expressed by a valid offer and acceptance; adequate consideration; capacity; and legality.
- Streamlined alternative to traditional procurement contracts, which can be more time-consuming and rigid.

Collaborative

- Allow for open and free-flowing negotiations rather than strict FAR negotiation structure.
- Increased collaboration and partnership between ARPA-H and partners, leading to more effective and efficient use of resources and knowledge sharing.

Flexible

- Many laws and regulations don't apply (e.g., CICA, FAR, CAS, Bid Protest, GAO Bid Protest, etc.).
- Greater flexibility in project design and implementation, allowing for more innovative and customized solutions.
- Invokes commercial practices, such as negotiating terms and conditions.
- May fully negotiate data rights, patents, payment structure, streamlined award process, etc.

Award Types – Procurement Contracts

FAR Contracts

- Unlike financial assistance, where the principal purpose is to transfer a thing of value to a recipient to carry out a public purpose of support or stimulation, a contract is used by the federal government to acquire property services for the direct benefit of the government.

Benefits

- Greater transparency and accountability, as the procurement process is subject to strict regulations and oversight to ensure fairness and integrity.
- Reduced risk of project failure or delays, as vendors are contractually obligated to deliver goods and services according to specific timelines and quality standards.

Process Overview

Abstract Submission

(BAA page 11)

- Cover should be marked "ABSTRACT."
- Length should not exceed 3 pages (excludes cover page, ROM & citations).
- Abstract should include all sections as specified in the BAA.
- Abstract evaluation criteria – scientific and technical merit, proposer's capabilities, and affordability.

Full Proposal

(BAA page 13)

- Must be invited to submit a full proposal based on abstract review.
- Volume I – Technical & Management.
- Volume II – Cost Proposal.
- Cover page - no more than one page in length.
- Summary of Proposal & Detailed Proposal Info – no more than 30 pages in length (excludes SOW).
- SOW – no page limit.

Evaluation and Selection

(BAA page 25)

- A scientific/technical review will be conducted of each abstract/proposal.
- Selection for award will be made based on evaluation criteria outlined in the BAA and availability of funding.

Evaluation Criteria

Overall Scientific and Technical Merit (Abstract and Full Proposal)

- Innovation.
- Feasibility.
- Achievability.
- Complete.
- Risk Mitigation Strategy.

Proposer's Capabilities and/or Related Experience (Abstract and Full Proposal)

- Relevant Expertise.
- Experience in Managing Similar Efforts.

Potential Contribution and Relevance to the ARPA-H Mission (Full Proposal)

- Relevance to Mission.
- Unmet Need.
- Future Application.

Evaluation Criteria (cont.)

Cost Realism/Price Reasonableness/Funding Availability/Affordability (Abstract and Full Proposal)

- Cost Realism.
  - Realistic for the work to be performed, reflect a clear understanding of the requirements, and are consistent with the unique methods and assumptions used by the contractor (e.g., not too low, match effort, etc.).
- Price Reasonableness.
  - Ensure the overall price is fair and reasonable (e.g., not too high).
- Availability/Affordability.
  - May only acquire goods or services that meet needs and are within budgetary constraints.
  - IP considerations.

What Makes for a High-Quality Submission?

Technical Merit

- Great Idea.
  - Aligns with ARPA-H's mission.
  - Revolutionary not Evolutionary.
- Doable.
  - Project objectives and expected outcomes are not just amazing but also supported by personnel, a methodology, plans for project and risk management, etc., that can take the idea from concept to reality.

Clarity and Conciseness

- Abstracts/proposals should be well-written, clear, and concise, with a logical flow and organized structure that makes it easy to understand the proposed work.

All Other BAA Requirements

- Eligibility (BAA pg. 9).
- Submissions should go to https://ecps.nih.gov/ (BAA pg. 21).
- Special requirements for cooperative agreement awardees (BAA pg. 22).
- Please read the BAA closely and carefully, there's a lot in there!

Innovative Technological Leaps

Common FAQs

Institution Type and Eligibility

- Entity, in terms of award limitations, is defined by the Unique Entity ID (UEI) and is not based on other relationships.
- The three ongoing concurrent awards with ARPA-H limit only applies to how many prime FAR procurement contracts an entity has with ARPA-H.
  - Does not apply to awards issued as cooperative agreements and/or OTs.
- The category for "Other Applicants" includes but not limited to:
  - Universities.
  - Businesses.
  - Non-profits.
  - Individuals.
  - Non-US entities (subject to the requirements included in the BAA, including in section III.A.2).
- ARPA-H does not have a preference with respect to entity type or team size.
- ARPA-H is limiting BAA awards to cooperative agreements, other transactions, and procurement contracts.
- There are no doctoral requirements as part of the BAA, however, proposals will be evaluated by the criteria laid out in the BAA including technical merit and performer capabilities.

Common FAQs

Award Limits (PoP, Budget)

- The Open BAA does not include a funding limit for individual awards.
  - Abstracts will be evaluated based on the criteria laid out in the solicitation, such as cost realism.
- The Open BAA does not include a limit or range for the period of performance for individual awards.
  - Proposers are encouraged to propose a budget that aligns with the scope of the proposed effort.
- The Open BAA does not include a maximum budget for the program or any individual focus area.
  - Resources made available under this BAA will depend on the quality of the proposals received and the availability of funds.

Submission Documents/Templates

- Citations to prior work do not count toward the 3-page abstract limit.
- The Cost Proposal spreadsheet will only be provided to entities when a full proposal is requested.
- Fields outlined in the BAA should be used for the Biosketch and Current/Pending Support; not NIH or other support templates.
- Abstracts must be received electronically by 3:00 PM EST by March 14, 2024, in order to be considered for further evaluation.
- ARPA-H is unable to accommodate individual requests for calls or meetings to discuss questions related to the Open BAA.
  - Please direct all general questions related to the Open BAA to **baaquestions@arpa-h.gov.**

Common FAQs

Scope of Proposed Concept

- ARPA-H is unable to accommodate individual requests for calls/meetings to discuss technical concepts being considered as a submission to the Open BAA.
  - ARPA-H will evaluate and provide feedback on a technical concept once it has been officially submitted in an abstract.
- In general, a clinical trial is eligible to be funded as part of a project awarded through the Open BAA.
- ARPA-H will not fund projects that exclusively involve clinical trials of otherwise developed products.
  - It is expected that the clinical trial would be proposed as part of a broader R&D effort that first includes development of a high-impact technology.
- ARPA-H will consider proposals that have a future commercial market; however, the goal of ARPA-H funding is to accelerate research that would not otherwise occur through existing commercial markets.

Rough Order of Magnitude (ROM)

- Cost sharing is not required (refer to section IV.A.4 of the BAA for more information).
  - Specifically, "for efforts with a likelihood of commercial application, appropriate direct cost sharing may be a positive factor in the evaluation."

baaquestions@arpa-h.gov.

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