Visit the ARPA-H **Sprint for Women's Health Website** and find more information about the sprint

Stay up to date with the latest ARPA-H news by subscribing to **ARPA-H Vitals**

Thank you for joining ARPA-H's Sprint for Women's Health Proposers' Day! The presentation will begin soon.
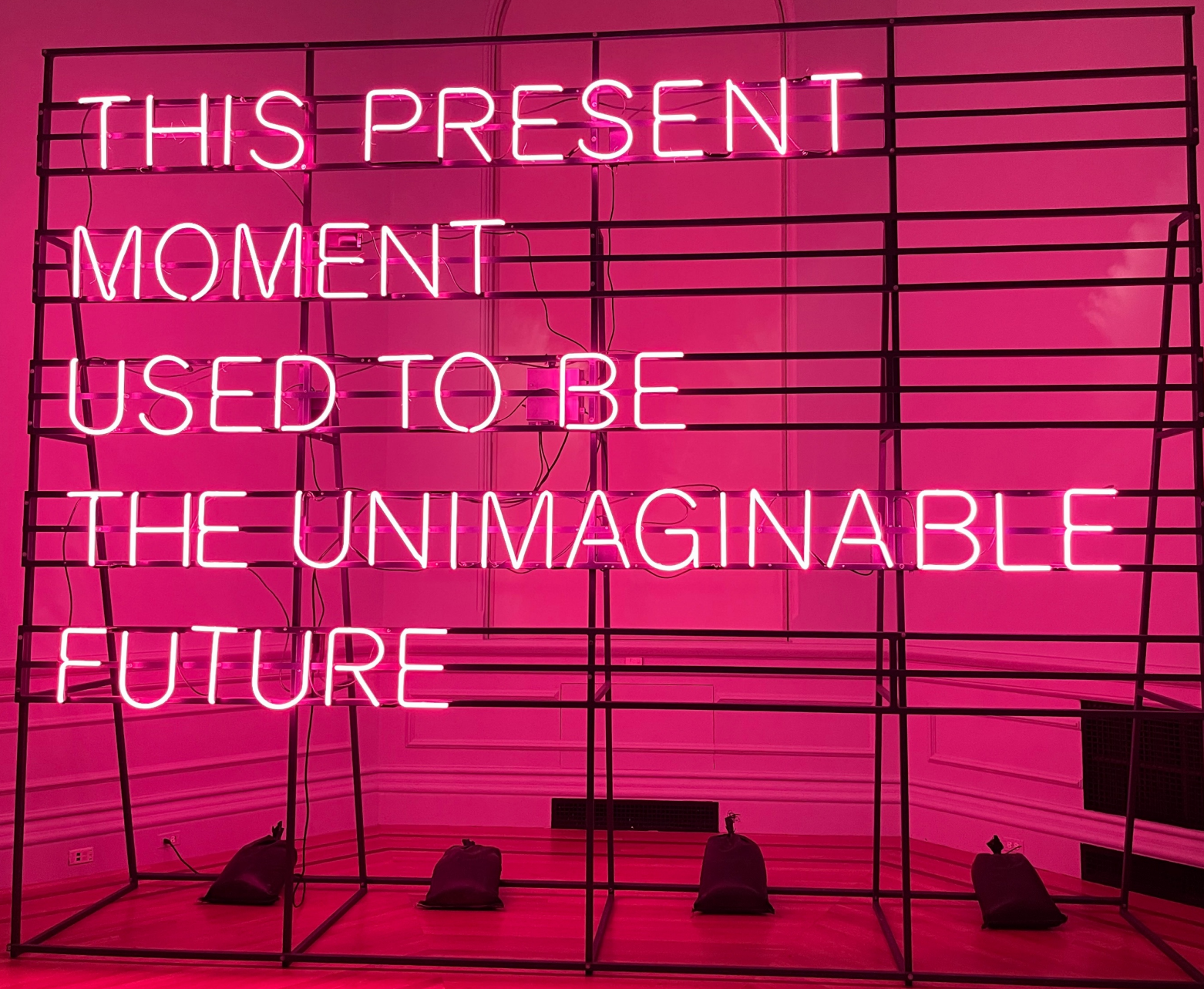
ARPA**H**

Sprint For Women's Health
Welcome and ARPA-H Model

Dr. Renee Wegrzyn

Director, ARPA-H

ARPA H

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

Mission

## Accelerate better health outcomes for everyone.
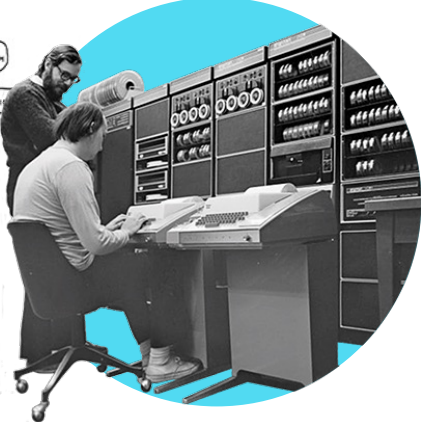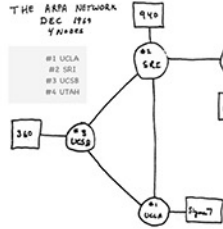
ARPA H

Why ARPA-H and Women's Health?

- Women represent more than half of our population (~167 million women) and make 80% of healthcare decisions
- Known gaps in diseases that uniquely impact women, investments in women's health research, and quality of women-specific data.

ARPA-H Objectives:
- <u>Address the Gaps</u> - ARPA-H's approach is particularly suited to move quickly, explore underfunded areas of women's health, and improve outcomes
- <u>Catalyze the Ecosystem</u> - We aim to derisk advancements to create a pathway for investors to invest in new discoveries and technologies in the women's health space
- <u>Testing New Business/Contracting Models</u> – maximizing authorities for B2B-like experience for proposers, lower the barrier for non-traditionals

ARPA H

The Promise of
the ARPA-H Model
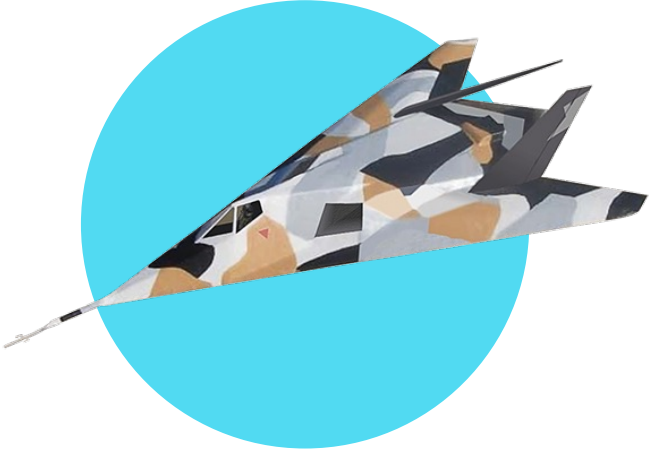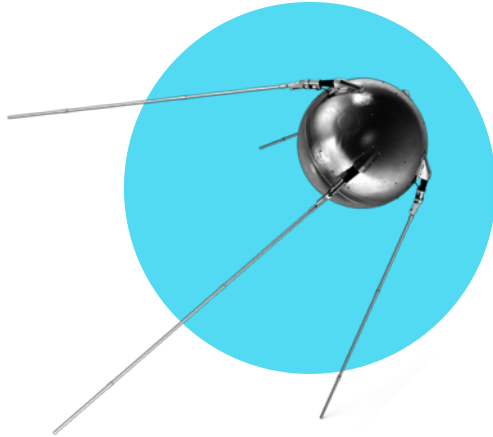
ARPA-H Key Features and Authorities
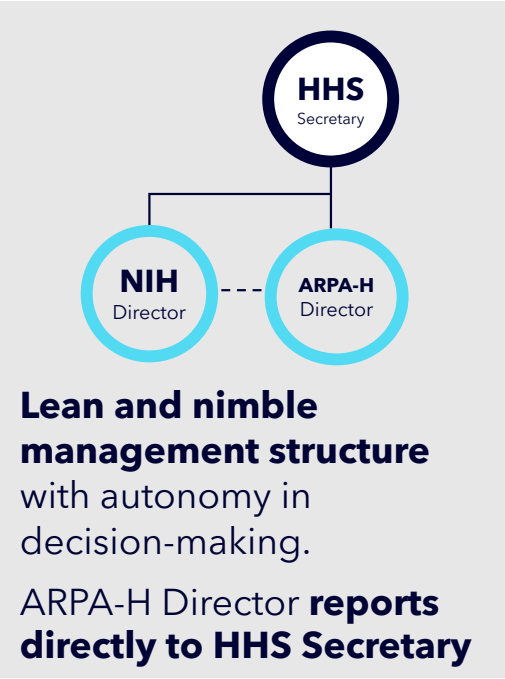
ARPA-H has unique structures and legal authorities that allow it to **function like a business – quickly, nimbly, and decisively**.

- Launched March 2022
- ARPA-H is a **funding agency**
- **Independent** component of HHS within NIH; not an Institute
- No internal research labs; **disease agnostic**
- **$2.5B appropriations**; budget independent from NIH
- Generally **fund outcome-based contracts,** not grants; accelerated award timelines
- **Bottoms-Up Problem Centric Approach** to address the toughest challenges in health

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

ARPA-H Director **reports directly to HHS Secretary**

Term limits of 3-6 years bring urgency and idea flow.

Flexibility in hiring allows ARPA-H to recruit at levels competitive with industry.

Bottom-up decision-making. PMs have autonomy to make decisions quickly**.**

ARPA-H is a problems focused organization

ARPA **H**

ARPA-H Agents for Change in Women's Health

ARPA-H PMs Daria Fedyukina, Kimberley Steele, Darshak Sanghavi, Ileana Hancu, and Jessica Green

Sprint for Women's Health Lead Jenica Patterson and PATIO Director Craig Gravitz

ARPA H

ARPA-H Accelerates the Entire Health Ecosystem

STAKEHOLDERS

The Public

NIH

Healthcare Providers

Federal Partners: FDA, CMS, HRSA, et al

CUSTOMERS

Patient Groups

Private Investors

PERFORMERS

Academia

Industry

NGOs

(and many others …)
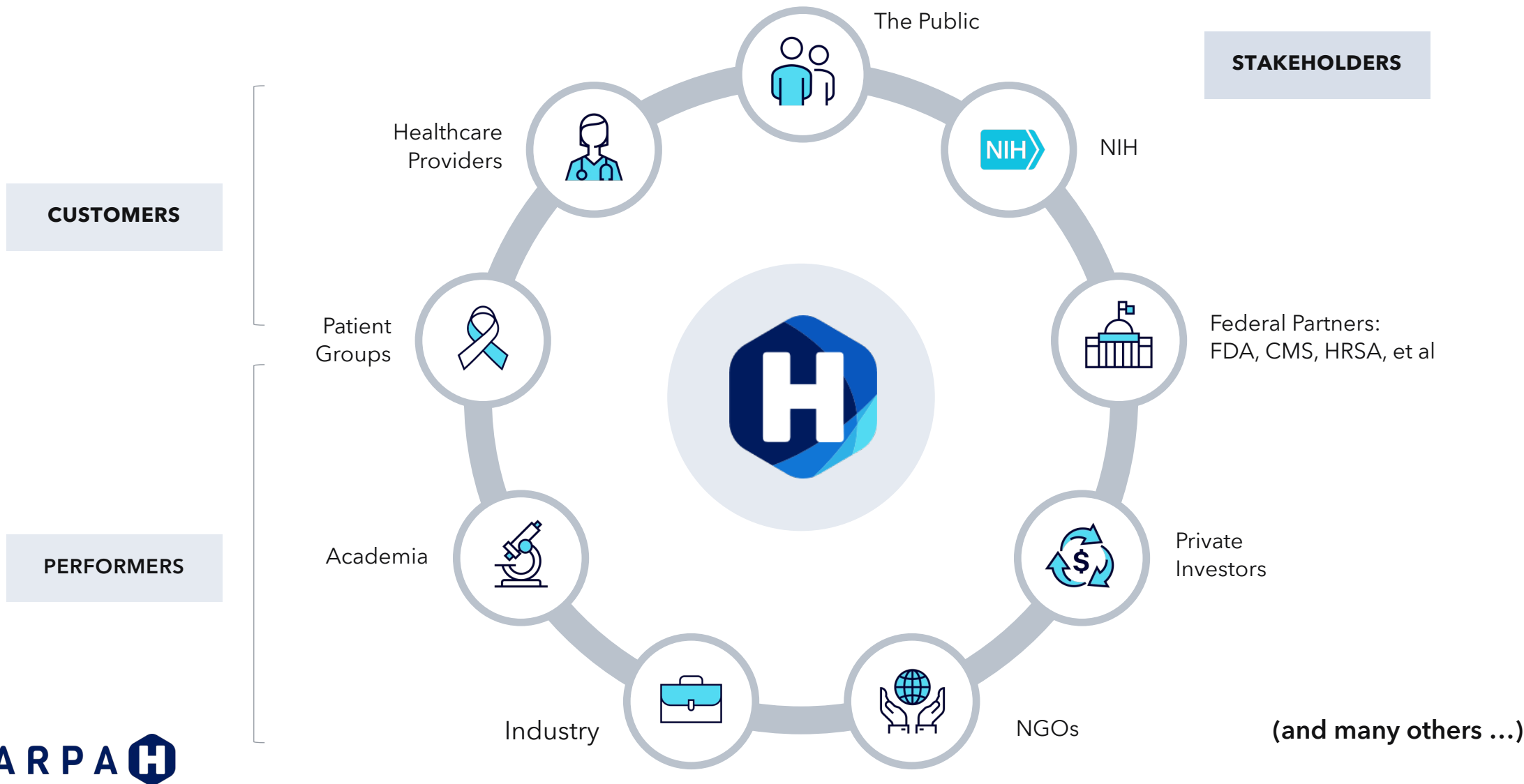
ARPA H

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? 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)?

ARPA**H**

Initial Mission Focus Areas

Project Accelerator Transition Innovation Office

Ensuring programs survive in the wild

Translating scientific and technical breakthroughs into real world products and services, ensuring they result in better health outcomes for all Americans

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.
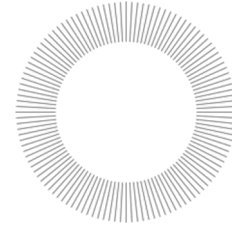
Proactive Health

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.
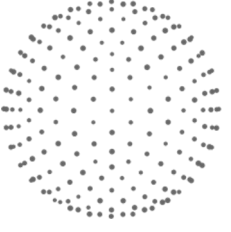
Resilient Systems

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.

ARPA H

ARPANET-H Network: Bridging disparate pieces of the health ecosystem & powering communities via ARPA-H

Stakeholder and Operations Hub

National Capital Region

Stakeholder engagements with our critical regulatory and legislative partners to support transitioning new health capabilities.

Example Stakeholders:
- regulatory (eg, FDA)
- USG payers (eg, CMS)
- Administrative Priorities (eg, WH Cancer Moonshot, HHS)

Customer Experience Hub

Dallas, Texas

Patient/customer community engagements and collaborations to meet the health needs of all Americans so solutions "survive in the wild".

Example Capabilities:
- advanced manufacturing
- clinical trials/centers
- community health labs
- testing and evaluation

Investor Catalyst Hub

Greater Boston, MA

Collaborations to accelerate the translation of innovative ideas into practical applications and transform patient care with sustainable investment.

Example Capabilities:
- market landscape analysis
- venture diligence
- incubator space
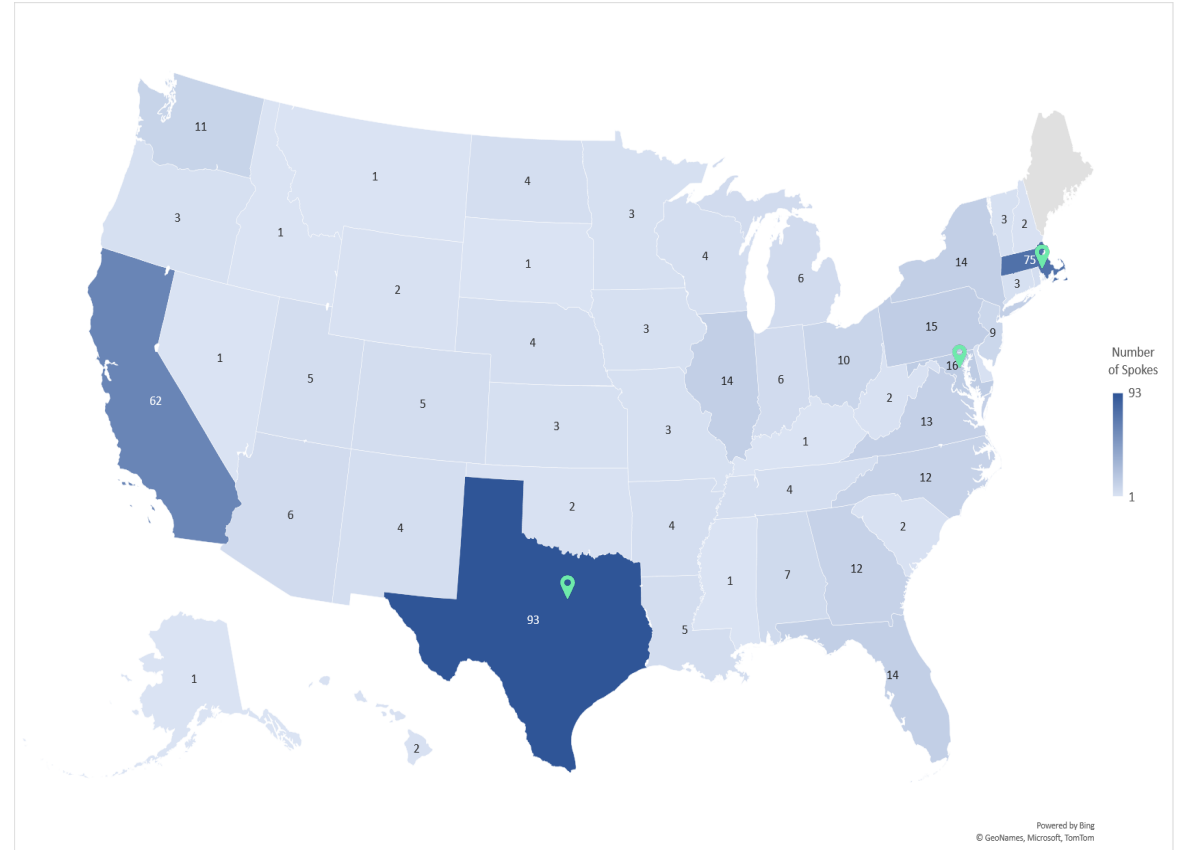
493 partners (spokes) and counting…

ARPA H

What if we could...

ARPA**H**

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

NITRO
Novel Innovations for Tissue Regeneration in Osteoarthritis

What if we could make our joints heal themselves?

REACT
Resilient, Extended, and Automated Cellular Therapies

What if your body could make its own medicine?

HEROES
HEalthcare Rewards to Achieve Improved OutcomES for All

What if we moved from a sick care system to a system that truly rewards better healthcare?

DIGIHEALS
Digital Healthcare Security

What if we had resilient healthcare infrastructure with advanced digital security for data, software, and devices?

PSI
Precision Surgical Interventions

What if surgeries fixed problems flawlessly, the first time?

PARADIGM
Platform Accelerating Rural Access to Distributed and Integrated Medical Care

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

SPIKEs
Synthetic Programable bacteria for Immune-directed Killing in tumor Environments

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

DARTS
Defeating Antibiotic Resistance through Transformative Solutions

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

CUREIT
Curing the Uncurable via RNA-Encoded Immunogene Tuning

What if uncurable diseases could be treated by tuning your immune system?

THEA
Transplantation of Human Eye Allografts

What if we could cure blindness?

ARPA H

The Project Accelerator Transition Innovation Office

Dr. Melissa Antman

Deputy Director, PATIO

ARPA H

Project Accelerator Transition Innovation Office (PATIO)

Our Mission: PATIO increases the probability that ARPA-H funded health technologies **will reach those Americans** by identifying barriers and providing transition and commercialization services to program managers and performers.

Feasible (technology)

Desirable (people)

Viable (business)

Innovation!
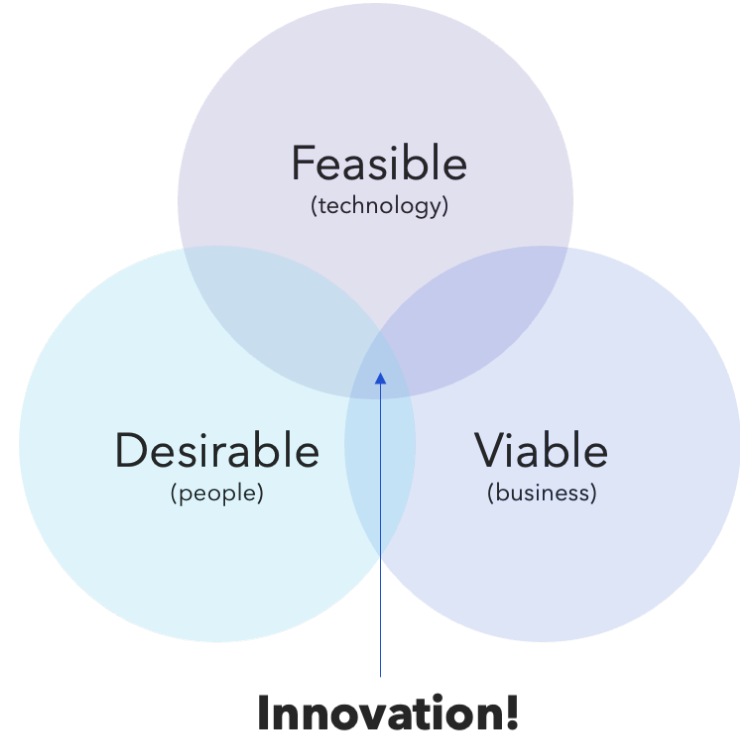
Since ARPA-H will not fund performers in perpetuity, PATIO's services increase the odds that solutions attract private investment and customers—to translate the breakthroughs

ARPA H

Where might the solution go after ARPA-H?
Work backwards: design with the end in mind

Large Established Company	Emerging Company with VC Backing	De Novo Startup	Health Care System
Other Gov Agency	Scaled NGO or Non-Profit	Startup NGO or Non-Profit	Fast Fail & Early Offramps

ARPA H

Our Capabilities
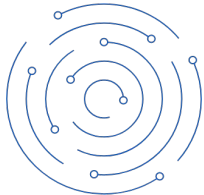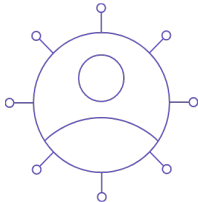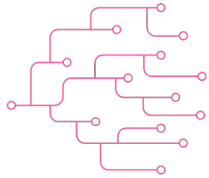
Technology Transfer and Transition Services (T3X)

Build transition-ready programs by de-risking solutions from program design through performance; leads the ARPA-H SBIR/STTR program

Led by Jenica Patterson, PhD

Health Ecosystem and Engagements Team (HEET)

Create meaningful bi-directional communication between ARPA-H and America.

Led by Dan Bram

ARPANET-H

Connect a fragmented health ecosystem through projects, events, and democratized learning

Led by Amy Lin

PATIO is led by Craig Gravitz (Director) and Melissa Antman (Deputy Director)

ARPA H

Join ARPANET-H!
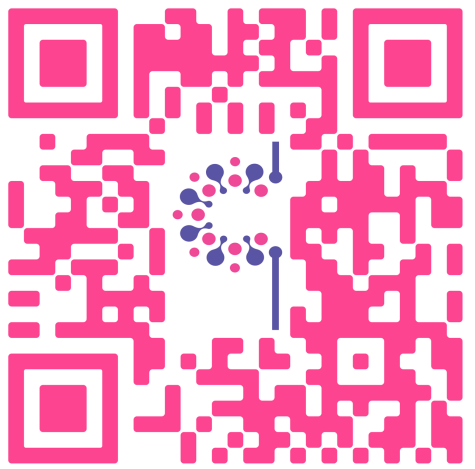
Customer Experience Hub Application

Investor Catalyst Hub Application

Spoke Application Process

- Fill out Application
- Sign Consortium Membership Agreement
- Application Review
- Acceptance Notification
- Complete Organization Profile:
  - Capabilities
  - Interest Areas
  - Partnership Opportunities

ARPA H

Sprint for Women's Health

Request for Solutions

Dr. Jenica Patterson

Sprint For Women's Health Lead

ARPA H

ARPA-H Investor Catalyst (IC) Hub
Part of the ARPANET-H Health Innovation Network

The ARPA-H IC Hub is supported by VentureWell

Location: Greater Boston area of Massachusetts

Accelerating Transformative Health Solutions

• Scales health research and venture investment ecosystem capabilities

• Disrupt traditional care models

• Create new delivery pathways

• Help performers bring game-changing solutions to market to solve big problems in health

A vast commercialization Network

• Offers opportunities for experts in government, industry, finance, healthcare, and academia to collaborate on medical breakthroughs

• Reach a broad spectrum of nonprofit organizations, Minority-Serving Institutions, and rural and urban settings

• Mobilize resources to accelerate and transition projects seamlessly into the commercial phase

Join the IC Hub Network

All proposers invited to the pitch phase will be required to become a network spoke

ARPA H

ARPA-H Sprint for Women's Health
Rapidly Identify & Solve High-Value Challenges

Problem Formulation

Open the aperture for Program Managers by cross-pollinating with experts from adjacent fields

De-risk Solutions.

Active program management with tough technical milestones where the government buys down technical, market, and business model risk

Target White Space.

ARPA-H identifies a health-related challenge that is both an unmet need for Americans and one that ARPA-H is not already addressing in its existing portfolio

Expert Discovery

Identify leading scientists and private sector experts to validate white space

Streamlined Funding

Make it easier to work with government: plain language, timely decision making, business to business style process, templated agreements

Launch.

If ARPA-H successfully buys down risk, the private sector (or other appropriate transition partner) will take on the solutions that we created

We are here

ARPA**H**

January 2024

January – February 2024

March 2024

Spring – Fall 2024

Fall 2024 – 2025

2025+

How It Works

Streamlined Funding. Make it easier to work with government: plain language, timely decision making, business to business style process, templated agreements

Request for Solutions

Proposers Day

3-page Solution Summary → Pitches → Down-selects

$100M in Awards

Innovation Across Timescales

TWO TYPES OF TRACKS

Spark
- Transformative, early-stage R&D efforts [Technical readiness levels (TRLs) 1-4]
- Awards of ~ **$3M**

Launchpad
- Transformative later-stage R&D efforts/early-stage startups (TRLs 5+)
- Awards of ~ **$10M**

ARPA H

What is a Spark?

- Spark awards will focus on transformative early-stage research efforts

- Aligned with Technical Readiness Levels (TRLs) 1-4 in the specific topics of interest in women's health.

- Selected performers will receive an ARPA-H award of approximately $3M.

TRL 1: Basic Principles Observed and Assessed
TRL 2: Health Concept and/or Use-Driven Experiments
TRL 3: Analytical and Experimental Critical Function and/or Characteristic Proof –of- Concept
TRL 4: Components are Validated in a Laboratory or Test Environment

ARPA H

What is a Launchpad?

Launchpad awards aim to accelerate later stage transformative health solutions reaching the public.

- ARPA-H award of approximately $10M

- Higher TRL stage (5+) where technical development is required but poised to impact health outcomes in the short term.

- Work with PM and Entrepreneur-In-Residence with commercialization and technology transition experience.

- Launchpad will work with performers to mature and grow their businesses through structured education, public and private resources, and domain specific mentorship.

TRL 5: Solution Prototype and/or System Components are Validated and Manufacturing Initiated

TRL 6: Prototype Demonstration in Relevant Health setting, Regulatory submissions, Clinical Data

TRL 7: Integrated Product Demonstration in a Real-world Environment, Process Validation, Initiation of GMP (when applicable)

TRL 8: Product Completed and Qualified through Test and Demonstration (FDA Clearance or Approval)

TRL 9: Product Successfully in Use and Operation

ARPA H

Topic Areas of Interest

Women's Health at Home

What if women were empowered to address their healthcare needs through diagnostics and treatments at home across all ages and stages of life?

Advancing Women's Brain Health via Lymphatic Targeting

What if targeting our brain's lymphatic system improved outcomes for women at risk for neurological and neurogenerative diseases?

Objective and Quantitative Measurement of Chronic Pain in Women

What if women's pain were taken seriously?

Wild Card: Revolutionary Breakthroughs in Women's Health

What if we could shatter the glass ceiling of women's health research with innovations so bold, they rewrite the rules of the game?

Prioritizing Ovarian Health Through Mid-Life to Prevent Disease

What if prioritizing ovarian health throughout a woman's life could actively prevent or delay the onset of a diverse array of acute and chronic conditions and diseases associated with peri-menopause and menopause?

ARTEMIS – Advancing Research Through Enhanced Models for Investigating the Influence of Sex Differences on Health Outcomes

What if we could revolutionize female-specific research models ensure equitable and effective treatments?

ARPA H

Key Timelines and Feedback

Important Dates to Remember

Mar 6, 2024	**Mar 27, 2024**	**April 15, 2024**	**April 2024**	**May-July 2024**	**July-Aug 2024**	**Sept 2024**
Proposers' Day	Questions Deadline	Solution Summary Due	Review Period Begins	Proposer Pitch Period	Invitation for Collaboration & Negotiation (IC&N)	**Awards Issued**

Proposers' Day

Teaming site active

March 13th – Submission portal live

ARPA H

Review Period Begins

Proposer teams selected to pitch will be notified

No written feedback will be provided

Invitation for Collaboration & Negotiation (IC&N)

Proposer teams selected to IC&N will be notified

No written feedback will be provided

Proposer Journey


```
Solution Summary Submission  --- Yes --->  Pitch Phase  --- Yes --->  Invitation for Collaboration & Negotiation  --->  Award

Solution Summary Submission --- No ---> Not Selectable Not Placed in Solution Library

Solution Summary Submission --- No, but deemed selectable ---> Submissions Library

Pitch Phase --- No, but deemed selectable ---> Submissions Library
```

Solution Summary Submission

Pitch Phase

Invitation for Collaboration & Negotiation

Award

Yes

Yes

No

No, but deemed selectable

No, but deemed selectable

Not Selectable Not Placed in Solution Library

Submissions Library

****There will NO be written feedback to proposers
All proposers will receive a SELECTABLE/NON-SELECTABLE
/Library answer**

Acquisition Details

The Application Process

Christina Mazzoli

Agreements Officer

Business Innovation Division (BID)

ARPA**H**

Award Types – Technical Direction Letter (TDL) under an Other Transaction (OT)

What are OTs?

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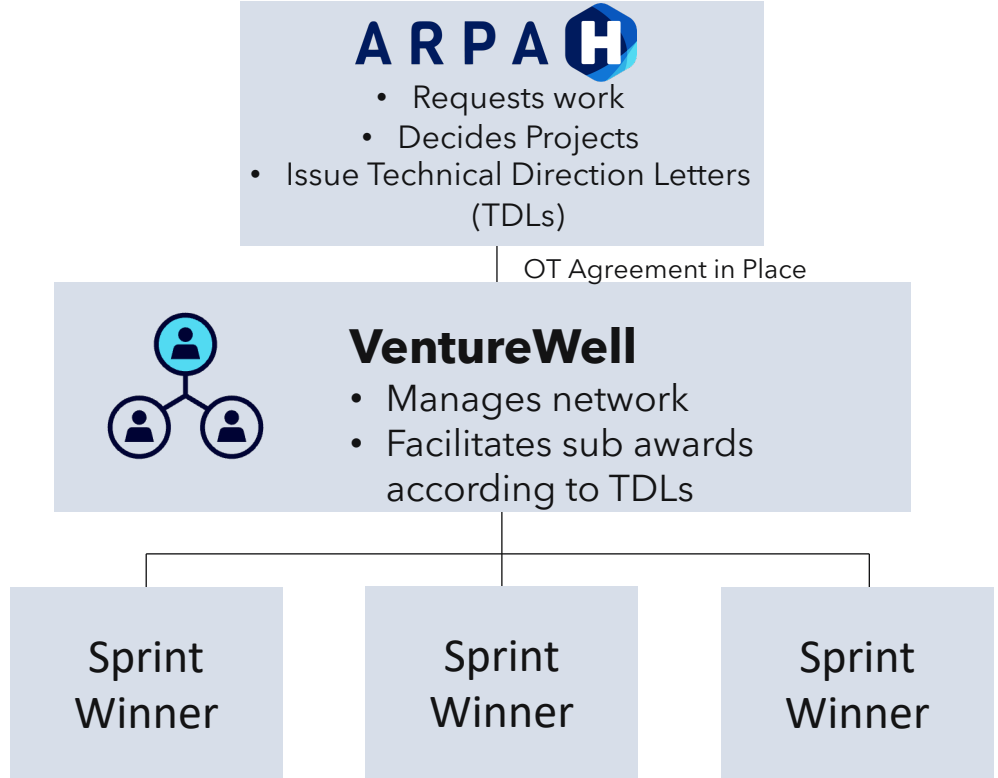
- OTs are contracts (e.g., mutual assent, expressed by a valid offer and acceptance; adequate consideration; capacity; and legality)

- OTs reflect commercial contracting rather than traditional FAR procurement contracts, grants, or cooperative agreements

How is an OT used for this solicitation?

ARPA H
- Requests work
- Decides Projects
- Issue Technical Direction Letters (TDLs)

OT Agreement in Place

VentureWell
- Manages network
- Facilitates sub awards according to TDLs

| Sprint Winner | Sprint Winner | Sprint Winner |

TDLs will be between the Investor Catalyst Hub, VentureWell and ARPA-H.
Subawards will be between the Investor Catalyst Hub, VentureWell and selected performer.

ARPA H

Submission Process

Solution Summary

ARPA-H will review submitted solution summaries (3pgs) based on the evaluation criteria

Solution summaries **must clearly align** to the solicitation topic for which they are being submitted and comply with all requirements detailed in the solicitation

All proposers will receive a **SELECTABLE/NON-SELECTABLE /Library answer** if they are moving to the pitch phase, not a written feedback response

Pitch

ARPA-H program managers will be the sole evaluator/decider for each pitch but may rely on additional insights from ARPA-H contracted support

Invited Pitches will be presented in **a slide deck format** with a Q&A following the pitch

A subset of pitch participants will be selected and will move forward in negotiations for an ARPA-H award. All proposers will receive a **SELECTABLE/NON-SELECTABLE /Library answer**

Invitation for Collaboration & Negotiation (IC&N)

After evaluating all the pitches, ARPA-H will notify proposers if they are selected to move to IC&N. The selected proposers will work with the PMs to collaboratively develop the following items:

- Scope of Work (SOW)
- Technical Milestones
- Project Timeline (or Period of Performance)
- If applicable, GFP/GFI
- Intellectual Property

Note: Further instructions will be provided for Pitch & IC&N Phases

ARPA H

Elements of a Solution Summary

A **3-page** solution summary should be submitted through the [ARPA-H Sprint for Women's Health Website](#). The solution summary should address **why the proposed idea is relevant to the ARPA-H mission** and the **proposed topic area** in women's health.

In addition, frame responses using the items:

1. Address the first 4 Heilmeier Questions (HQs)
2. Team qualifications
3. R&D timeline (24 months)—what you can accomplish in the agreed upon project timelines?
4. Rough order magnitude (ROM)

Proposers will only be notified about whether their submission is selectable / non-selectable or eligible for the Library

Basic Information Included

- Solution Summary Title:
- Topic Area Number
- Organization Name:
- Organization Address:
- Website:
- Point of Contact Name:
- Point of Contact Email Address:
- Point of Contact Phone Number:
- Team Members including the makeup of the leadership team, any key personnel, core competencies and Levels of effort.
- Do you plan to team with or subcontract to another organization to execute this effort? Please describe.
- **Are you applying for the Spark or Launchpad track?**

Applicable for Launchpad only :
- Is the proposer a commercial entity? What is the business structure (e.g., LLC, S-Corp, C-Corp, Academic Lab)?
- If you have taken foreign investment, please list any international investors (w/ country)

ARPA **H**

ARPA-(H)eilmeier Questions For Solution Summary
Towards a well-defined problem

1 What are you trying to do? What health problem are you trying to solve? *"What if...."*

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)?

Solution Summaries will be expected to answer HQs 1-4

ARPA H

Elements of a Pitch

A proposing team will present their idea to the ARPA-H team in a **slide deck format**, with a question and answer (Q&A) session following the pitch.

Proposers will need to:

- Address all 10 HQs

- Meet the evaluation criteria outlined in the Request for Solutions

- Become a spoke in the ARPANET-H Investor Catalyst Hub – *instructions to be provided later*

The ARPA-H PM is the sole evaluator/decider on whether or not a pitch will move to the Collaboration & Negotiation phase.

*Templates will be provided to those selected for the pitch phase

Important to Note

- The government will not pay proposers for costs associated with pitches unless otherwise stipulated
- ARPA-H reserves the right to limit the number of proposers invited to the Invitation for Collaboration & Negotiation (IC&N) phase
- A pitch may be evaluated to be of merit but not selected for the IC&N phase and subsequently eligible to be placed into the "Submissions Library"

ARPA H

ARPA-(H)eilmeier Questions For Pitches

Towards a well-defined problem

1 What are you trying to do? What health problem are you trying to solve? *"What if...."*

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)?

Pitches will be expected to answer ALL HQs

ARPA H

Evaluation Criteria

- ARPA-H will use the same criteria to evaluate Solution Summaries and Pitches.

- Technical Merit takes precedence, submissions lacking Technical Merit will not be evaluated further.

- Submissions with Technical Merit, will be evaluated based on the remaining criteria listed below.

- All proposers will be notified if their submission is SELECTABLE / NON-SELECTABLE or eligible for the Submissions Library

Technical Merit	User Experience	Commercial Viability	Team	Pricing
The proposed solution identifies clear, measurable goals that have a reasonable chance of meeting the topic objectives.	The proposed solution contemplates the end user, first by understanding for whom the solution solves. The solution meets the needs of the end user, whether patients, providers, health systems, or payers.	The potential of the proposed solution for commercial application and proposed methods of overcoming potential barriers to entry in the competitive market landscape.	The qualifications of the proposer team in terms of technical expertise and commercial acumen include the makeup of the leadership team and the key personnel.	*Solution Summary and Pitch*: Rough Order of Magnitude (ROM) pricing will be evaluated for affordable /non-affordable. *IC&N*: Evaluate pricing for reasonableness.

ARPA H

Submissions Library

What is it?

- Repository of highly rated technical submissions available for future selection.
  - Submissions with Technical Merit but not invited to Pitch or Negotiations may be placed in the Submissions Library.

Who maintains it?

- Investor Catalyst Hub, VentureWell along with the ARPA-H Agreements Officer and Agreements Specialist.

How long are submissions valid?

- Submissions in the in the Submissions Library 18 months from submission date.

What are the requirements for inclusion in the Submissions Library?

- Only approved Spokes evaluated as selectable can be placed into the Submissions Library.

By submitting a Solution Summary, the proposer agrees that if their submission is placed in the Submissions Library it may be shared with other federal agencies for award.

ARPA H

Teaming
Facilitating connections between perspective performer teams

ARPA-H anticipates that teaming will be necessary to achieve the goals of the program, thus we encourage perspective proposers to form teams with varied technical experience to submit a Solution Summary.

Q: Do you need to have a specific partner(s) from industry, academia, etc.?

A: No, any mix of institutions/organizations is allowed.

Q: Can one group be part of multiple Solution Summaries?

A: Yes, one group can be part of multiple Solution Summaries, however each lead can only submit one Solution Summary per topic.

Q: Is there a limit to how many institutions can team?

A: No, there is no limit on how many institutions can team.

Q: Will you establish teams for us?

A: No, your information will be publicly available to all other interested organizations. It is your responsible to reach out to other organizations you are interested in teaming with.

Q: Can the same proposer or proser team submit a Solution Summary to multiple topics?

A: Yes, a proposer or team can submit to multiple topics. However, only one Solution Summary can be submitted per PI/Lead per topic.

Visit the Teaming Page

*ARPA-H is not endorsing, sponsoring, or otherwise evaluating the qualifications of the organizations or individuals included on the teaming page

ARPA **H**

ARPA-H's Sprint for Women's Health Topics of Interest

ARPA-H Program Managers (PMs)

ARPA H

Topic 1: Women's Health at Home

Darshak Sanghavi, M.D.
Resilient Systems Office

What If Statement

What if women were empowered to address their healthcare needs through diagnostics and treatments at home across all ages and stages of life?

Key Outcomes

- Technologies for novel home-based preventative care that is faster, cheaper, and more effective than usual care
- Meaningfully improve health outcomes for women who typically lack access for both diagnosis and treatment
- Dramatically Improve women's satisfaction and experience of care with well-designed, highly engaging programs

Problem Statement

ARPA-H seeks transformative technologies to diagnose and/or treat multiple women's health issues in the home

Requirements and Considerations

- **Breakthrough platforms** that monitor, diagnose, administer, treat, or maintain healthy status across all ages and stages of women's health
- Should let women ideally both detect and treat disease in the **privacy of their own home**
- Dramatically improve quality of life **by decreasing the complexity and time spent trying to get healthcare**
- **Measurably improve** high value health outcomes

✓ Devices or wearable sensors to assess breast, hormonal, cervical, and pelvic health; diagnose infectious disease (UTIs, STDs); vaginal specimen collection and drug delivery innovations

✓ Predicting and preventing premature labor; postpartum health; mental health and wellness; nutritional support; maternal health; innovations in telehealth

✗ Incremental or iterative telehealth or home testing concepts that are already well-funded or developed

ARPA **H**

Topic 2: Prioritizing Ovarian Health Through Mid-Life to Prevent Disease

Jessica Green, PhD
Resilient Systems Office

What If Statement

What if prioritizing ovarian health throughout a woman's life could actively prevent or delay the onset of a diverse array of acute and chronic conditions and diseases associated with peri-menopause and menopause?

Key Outcomes

- Increased understanding of ovarian aging in the context of other body systems (neuro, osteo, cardio, etc.)
- Reduction in perimenopause and menopause symptoms
- Reduction in chronic conditions attributed to ovarian function decline and fluctuation of hormones

Problem Statement

ARPA-H seeks revolutionary solutions to **promote ovarian health and preserve endocrine function** past mid-life, thereby **enhancing women's health over the life span** and proactively addressing both short and long-term health effects associated with menopause and ovarian aging. This initiative aims to:

- Explore novel treatments, interventions, and research that prioritize conservation of ovarian function, maintaining or restoring hormone levels, including solutions that promote natural ovarian health beyond mid-life.

- Prevent and mitigate diseases and conditions associated with women's aging, ensuring a healthier and extended quality of life.

Promising innovations may include but are not limited to:
- ✓ Safe and accessible pharmaceutical interventions
- ✓ Cell and gene therapies
- ✓ Implantable bioelectronics
- ✓ At-home solutions for monitoring and adjusting hormone levels as a companion to interventions
- ✗ Topics that address fertility or extended reproductive age

ARPA H

Topic 4: Advancing Women's Brain Health via Lymphatic Targeting

Kimberley Steele, MD, PhD
Health Science Futures
Office

What If Statement

What if targeting our brain's lymphatic system improved outcomes for women at risk for neurological and neurogenerative diseases?

Key Outcomes

- Early diagnosis and detection of neurological and neurodegenerative diseases.
- Improved opportunities for preventative care informed by the unique phenotype of the disease in women.

Problem Statement

ARPA-H aims to catalyze **neurological and neurodegenerative disease** research by investing in innovative technology that addresses the key challenges in **meningeal lymphatics and glymphatics** research, diagnosis, treatment, and care. All proposed solutions should be developed to ensure fit to the **onset, phenotype, and presentation** of these disease states in women.

- Novel Diagnostics:
  – Leverage the unique physiology and draining functions of the lymphatic and glymphatic system to develop novel diagnostic tools, such as **imaging modalities and biomarker detection**.

- Innovative Therapies:
  – **High throughput drug studies**, using state of the art drug discovery approaches, to identify compounds that can reliably modulate meningeal lymphatic function.
  – Therapeutic technology that **enhances removal of toxic waste products** that are implicated in the etiology of neurological disease or neurodegeneration.

- Platform Development:
  – Understand the variability in lymphatic vasculature **based on sex and age** that could inform the pathology of neurological and neurodegenerative disease.

✓ Innovative technology targeting brain lymphatics
✗ Other solutions targeting women's brain health (submit to Topic 6)

ARPA H

Topic 5: Objective and Quantitative Measurement of Chronic Pain in Women

Ileana Hancu, PhD
Health Science Futures Office

What If Statement

What if women's pain were taken seriously?

Key Outcomes

- A device, a method or a system to quantify an individual's pain over time
- A pain management tool for clinicians to determine the efficacy of current treatments and next best steps
- A research tool to conduct more consistent clinical trials
- A tool to quantify and support a patient's claims about their comfort and wellbeing
- Increased understanding of pain management and decreased use of opioids.

ARPA H

Problem Statement

Develop methods to **objectively, quantitatively and longitudinally measure pain** across a variety of chronic conditions, including nociceptive pain, neuropathic pain, and pain due to central nervous system sensitization. This will enable clinicians to evaluate disease evolution and to determine how well a patient's course of treatment is addressing their pain.

Requirements and Considerations

Psychosocial factors: gender, background, and life circumstances affect a person's response to pain (e.g., a person who cannot afford to skip a day of work may force themselves to be more mobile despite high pain levels).

Patient support: women's pain is too often ignored, minimized, or dismissed. The method must agree with self-reported assessments.

Access and comfort: The method should be simple and inexpensive. *At-home monitoring methods and wearables are encouraged*.

Streamlined solutions: Markers should belong to one source (e.g. blood)-[preferred] or two [acceptable]. For example:
- ✓ Sweat and blood biomarkers or wearable and urine, non-invasive
- ✗ MRI exam + genomic screen + blood-based biomarkers + urine-based biomarkers is too complex

Topic 3: ARTEMIS – Advancing Research Through Enhanced Models for Investigating the Influence of Sex Differences on Health Outcomes

Daria Fedyukina, Ph.D.
Health Science Futures Office

What If Statement

What if we could revolutionize female-specific research models to ensure equitable and effective treatments?

Key Outcomes

- Platform technologies for de-risking preclinical and clinical research to improve health outcomes for women.
- Increased understanding of sex-specific biological differences to inform diagnostic and therapeutic technologies and improve outcomes for women

Problem Statement

ARPA-H aims to catalyze the **development of innovative living and digital female-specific model platforms**, which are tailored and optimized to study women's health issues. The aim is to enable a transformative leap forward in how women's health issues are modeled and subsequently addressed. While developing models, the platform technology should **adequately represent female biology and physiology**, e.g., the reproductive system, hormonal fluctuations, genetic and epigenetic differences between males and females, behavioral and psychological factors that may influence research outcomes, or any combination of these.

Solutions

- Develop <u>healthy models</u> that emulate the response of a tissue, organ, or organ system that is critical for women's health.
- Develop <u>disease models</u> that accurately mimic how diseases manifest and progress in females, considering conditions that predominantly affect women or present differently in women compared to men.
- Facilitate an improved understanding of <u>disease heterogeneity</u> based on sex and gender.
- Include novel features, functions, and design choices that improve the ability to <u>predict the response of women to interventions</u>.

ARPA H

Topic 6: WILD CARD: Revolutionary Breakthroughs in Women's Health

Jenica Patterson, Ph.D.
Project Accelerator
Transition Innovation
Office

What If Statement
What if we could shatter the glass ceiling of women's health research with innovations so bold, they rewrite the rules of the game?

Key Outcomes/Areas of High Interest

- Brain Health

- Advancing Data Methodologies, Data Access, Data Value Chain

- Other catalyzing breakthroughs

ARPA H

Problem Statement

ARPA-H acknowledges the critical gaps in data, historical underrepresentation in clinical trials, and lack of focused research on unique health needs of women. Therefore, we aim to:

- Catalyze breakthroughs that will transform the paradigm of women's health

- Revolutionize the methodologies for data generation, analysis, and application in women's health.

- Forge personalized and effective strategies, addressing the comprehensive and specific health challenges women face.

✓ **Novel technologies, new business models, revolutionary data approaches**
✗ Iterative and standard approaches
✗ Traditional clinical trials
✗ Well-supported work by private and public investment
✗ Solutions that address Topics 1-5

Frequently Asked Questions (FAQs)

Please read the entire RFS and the FAQ's prior to submitting questions.

RFS questions will be answered via the FAQ's that get published on https://sprint.investorcatalysthub.org/request-for-solutions/

- All inquiries shall be sent to the FAQ page

- Write questions as clearly as possible

- Do not include proprietary information

- ARPA-H may re-phrase questions or consolidate similar questions for administrative purposes.

- ARPA-H may be unable to respond to questions submitted less than 10 business days in advance of the submission deadline.

- If there is a contradiction between the FAQ and the RFS, defer to the RFS.

Scan for FAQ site

ARPA H

FAQs To Date: Awards and Eligibility

Q: How many solutions will be funded under the Sprint for Women's Health and each funding track or topic area?

A: We seek to fund up to $100M in awards. We do not have a defined number of awards by funding track or topic area.

Q: Will each funding tracks fund IRB studies on human subjects?

A: Yes. Pay special attention to the requirements concerning Human Subjects and use of Vertebrate Animals.

Q: Do you have to be a US-based company to be eligible? Do you have to partner with US-based companies to be eligible?

A: No.

Q: Do you have to be a member of the Investor Catalyst Hub to receive funding?

A: Yes.

Q: Will there be prioritization for solutions summaries that prioritize women's health conditions that have less federal research relative to the burden of disease?

A: Evaluation of Solution Summaries and Pitches will be based on Technical Merit, User Experience, Commercial Viability, Team, and Pricing criteria. Prioritization will be based on these criteria. Overlap in federal funding will be addressed.

ARPA H

Next Steps

1 Submit any questions you may have through the FAQs website **https://investorcatalysthub.swoogo.com/womenshealth_faq/**

2 Begin teaming with other proposers **https://sprint.investorcatalysthub.org/teaming-profiles**

3 Submit your Solution Summary by April 15, 2024 12pm ET

ARPA**H**

Visit the ARPA-H **Sprint for Women's Health Website** where you can read the Request for Solutions, submit your Solution Summary, and find more information about the sprint

Stay up to date with the latest ARPA-H news by subscribing to **ARPA-H Vitals**

THANK YOU!

Equity Considerations

Equitable access to health tools has multiple considerations that need to be incorporated FIRST.

Research will include benchmarks for equity.

Inclusion

- Access, equity, and affordability built-in Target Product Profile
  - Efficacy, administration route, dose, shelf-life, and cost
- Engage with PATIO to initiate research via CX HUB on relevant to non-traditional additions needed for an "**American**/Universal" **TPP** – preliminary TPP delivered within first year of performance
- Including desired targets that are relevant in both the U.S. and globally is essential for creating a more equitable sharing system and fair distribution

Development

- Product considerations included up front
  - Platform technologies targeted here create candidates with greater chance of success
- Vaccine development community will have data and tools dedicated to viral antigen engineering for future MCM discoveries
- Open-source toolkit – and the positive and negative training data used to build the toolkit – will be made broadly accessible

ARPA H

TPP: Target Product Profile, **MCM**: Medical countermeasure

Intellectual Property

Who will own the IP?

Generally, the government does not take ownership of intellectual property produced under awards.

For **Other Transaction Agreements**, there is more flexibility, and IP will be subject to negotiations between the proposer and ARPA-H.

At a minimum, ARPA-H wants to ensure that IP restrictions do not keep breakthrough technologies from the people who can benefit from them

ARPA H

Equity Considerations

Inclusion

- Access, equity, and affordability built-in Target Product Profile
    - Efficacy, administration route, dose, shelf-life, and cost
- Including desired targets that are relevant in both the U.S. and globally is essential for creating a more equitable sharing system and fair distribution
- Equity considerations will be required to be addressed in the pitch phase. We will ask that all proposers selected to pitch address HQ9 To ensure equitable access for all people, how will cost, accessibility, and user experience be addressed?

ARPA-H Model: Program Lifecycle

Launch

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

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

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

Performers
Performers compete to carry out their potential innovative solutions to the challenge.

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.

Perform

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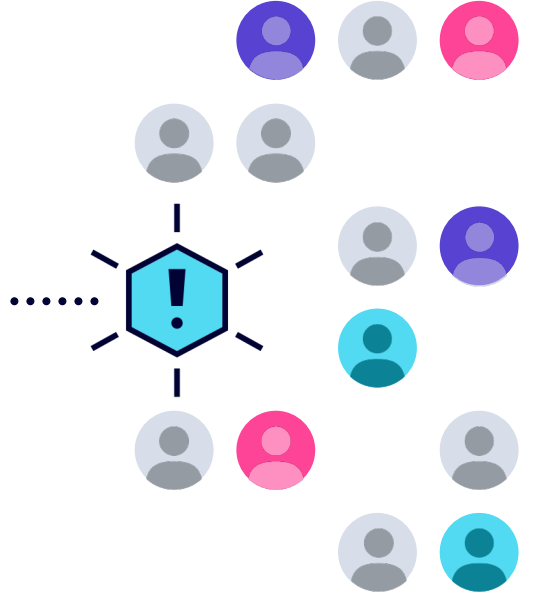
Graduation
Graduation occurs when the challenge is solved. The project then transfers to partners, who have been involved from the start and can scale the solution for large, diverse communities everywhere.

ARPA H

Evaluation Rubric

The PM will use the criteria to determine overall if the submission is Selectable or Not Selectable.

	Description
Technical Merit	The proposed solution identifies clear, measurable goals that have a reasonable chance of meeting the topic objectives. The potential of the proposed solution for technological innovation – whether the end-product or technology proposed would offer significant advantages over existing approaches, methodologies, instrumentation, or interventions currently used in research or clinical practice. Further, the proposed solution should align with the ARPA-H mission.
User Experience	The proposed solution contemplates the end user, first by understanding for whom the solution solves. For example, who will use this? Second, the solution meets the needs of the end user, whether patients, providers, health systems, or payers. For example, how would this solution fit inside the current clinical workflow? Or, how will this be accessible to users in all geographies, and at an affordable cost?
Commercial Viability	The potential of the proposed solution for commercial application and proposed methods of overcoming potential barriers to entry in the competitive market landscape include factors like whether there is an existing market for the solution, the size of the market, viable regulatory pathway, reimbursement, pricing strategy, competitive landscape, cost of production, business model, and revenue potential.
Team	The qualifications of the proposer team in terms of technical expertise and commercial acumen include the makeup of the leadership team and the key personnel and take into account their approach: designated roles and responsibilities, governance, and organizational structure, as well as that of their supporting staff, consultants, advisors, and partners.
Pricing	For Solution Summary and Pitch Phases: Rough Order of Magnitude (ROM) pricing that describes the basic unbundled prices. It shall encompass all known costs associated with the proposed effort. Will be evaluated for affordable /non-affordable (if provided or if not). For the IC&N Phase: ARPA-H will evaluate pricing for reasonableness.

ARPA H