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.
Thank you for joining ARPA-H’s Sprint for Women's Health Proposers’ Day! The presentation will begin soon.
Sprint For Women’s Health
Welcome and ARPA-H Model

Dr. Renee Wegrzyn
Director, ARPA-H
Alicia Eggert
This Present Moment
2019 - 2020
Currently @ The Renwick Gallery
Washington, DC
Mission

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

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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 Accelerates the Entire Health Ecosystem

CUSTOMERS
- Healthcare Providers
- Patient Groups
- Academia
- Industry
- NGOs

PERFORMERS
- Federal Partners: FDA, CMS, HRSA, et al
- Private Investors
- STAKEHOLDERS: The Public

(AND MANY OTHERS …)

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# 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)?**
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.
ARPANET-H Network: Bridging disparate pieces of the health ecosystem & powering communities via ARPA-H

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)

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

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...
What if we could...
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 programmable 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?

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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.

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.
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
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)

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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
Sprint for Women's Health
Request for Solutions

Dr. Jenica Patterson
Sprint For Women’s Health Lead
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
Sprint for Women’s Health

ARPA-H is committing $100 million to galvanize the innovator, investor, researcher, and patient advocate communities to spur innovation in women's health.

What If we could shatter the glass ceiling of biomedical and health research to improve health outcomes for women?
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.

Problem Formulation

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

Streamlined Funding

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

De-risk Solutions.

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

Launch.

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

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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
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

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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?

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?

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?

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?
**Key Timelines and Feedback**

**Important Dates to Remember**

- **Mar 6, 2024**: Proposers’ Day
  - Teaming site active
  - Questions Deadline

- **Mar 27, 2024**: Submission portal live

- **April 15, 2024**: Solution Summary Due

- **April 2024**: Review Period Begins

- **May-July 2024**: Proposer Pitch Period

- **July-Aug 2024**: Invitation for Collaboration & Negotiation (IC&N)
  - No written feedback will be provided

- **Sept 2024**: Awards Issued
  - Proposer teams selected to IC&N will be notified
  - No written feedback will be provided
**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)
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
- ARPA-H decides projects
- ARPA-H issues Technical Direction Letters (TDLs)
- VentureWell manages network
- VentureWell 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.
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

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.

Submission Process
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)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
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)eilmeier Questions For Pitches

Towards a well-defined problem

<table>
<thead>
<tr>
<th>Question</th>
<th></th>
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<tbody>
<tr>
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<td></td>
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Pitches will be expected to answer ALL HQs
**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.

<table>
<thead>
<tr>
<th>Technical Merit</th>
<th>User Experience</th>
<th>Commercial Viability</th>
<th>Team</th>
<th>Pricing</th>
</tr>
</thead>
<tbody>
<tr>
<td>The proposed solution identifies clear, measurable goals that have a reasonable chance of meeting the topic objectives.</td>
<td>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.</td>
<td>The potential of the proposed solution for commercial application and proposed methods of overcoming potential barriers to entry in the competitive market landscape.</td>
<td>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.</td>
<td>Solution Summary and Pitch: Rough Order of Magnitude (ROM) pricing will be evaluated for affordable /non-affordable. IC&amp;N: Evaluate pricing for reasonableness.</td>
</tr>
</tbody>
</table>
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 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.
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’s Sprint for Women’s Health Topics of Interest

ARPA-H Program Managers (PMs)
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
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

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

What If Statement
What if targeting our brain’s lymphatic system improved outcomes for women at risk for neurological and neurodegenerative 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)
Topic 5: Objective and Quantitative Measurement of Chronic Pain in Women

Ileana Hancu, PhD
Health Science Futures Office

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

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.

Ileana Hancu, PhD
Health Science Futures Office

Ileana Hancu, PhD
Health Science Futures Office
Topic 3: ARTEMIS - Advancing Research Through Enhanced Models for Investigating the Influence of Sex Differences on Health Outcomes

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 healthy models that emulate the response of a tissue, organ, or organ system that is critical for women’s health.
• Develop disease models 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 disease heterogeneity based on sex and gender.
• Include novel features, functions, and design choices that improve the ability to predict the response of women to interventions.

Daria Fedyukina, Ph.D.
Health Science Futures Office
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

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.

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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.
Next Steps

1. Submit any questions you may have through the FAQs website [https://investorcatalysthub.swoogo.com/womenshealth_faq/](https://investorcatalysthub.swoogo.com/womenshealth_faq/)

2. Begin teaming with other proposers [https://sprint.investorcatalysthub.org/teaming-profiles](https://sprint.investorcatalysthub.org/teaming-profiles)

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

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.

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**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?

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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.

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.

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

Performance
Contract performance will be regularly evaluated to allow ARPA-H to concentrate resources on the most effective approaches to reaching the desired goals.

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.

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

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

<table>
<thead>
<tr>
<th>Evaluation Categories</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Technical Merit</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>User Experience</strong></td>
<td>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?</td>
</tr>
<tr>
<td><strong>Commercial Viability</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Team</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>
| **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. |