

**THE ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH (ARPA-H)
SPRINT FOR WOMEN’S HEALTH REQUEST FOR SOLUTIONS (RFS)**

Solicitation #: ARPA-H-ICHUB-24-101

Amendment: 02

Edits highlighted in yellow

IMPORTANT DATES:

Virtual Proposers Day: March 6th: The government will hold a [virtual proposers day](#) via Zoom on March 6th. We will provide an overview of the Request for Solutions (RFS) with an opportunity to ask questions and access teaming opportunities.

Question Deadline: The government must receive questions by **March 27th, 2024, 5:00 PM EDT**. Please send questions to the Sprint for Women’s Health [FAQ submission page](#).

Submission Deadline: The government must receive Solution Summaries by **April 15th, 2024, 12:00 PM EDT**.

Please read the entire RFS carefully prior to submitting your Solution Summary.

IMPORTANT: All Solution Summaries must be submitted electronically using the portal at sprint.investorcatalysthub.org

Paper proposals will not be accepted

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1. INTRODUCTION: ARPA-H Sprint for Women's Health

The Advanced Research Projects Agency for Health (ARPA-H) supports biomedical and health research breakthroughs that can deliver transformative, financially sustainable, and broadly applicable health solutions for everyone. ARPA-H aims to address critical unmet challenges in women's health across all demographics, geographies, and socioeconomic statuses, championing transformative innovations and tackling health conditions that uniquely or disproportionately affect women from every walk of life. Through the Sprint for Women's Health, ARPA-H aims to galvanize the innovator, investor, researcher, and patient advocate communities to proactively address women's health challenges, raise awareness, and spur innovation with two major funding opportunity tracks. The two funding opportunity tracks aim to foster transformative R&D efforts from early-stage research "Spark" to later-stage development "Launchpad" that impact and improve women's health outcomes. With the two funding opportunity tracks, ARPA-H aims to lower barriers of entry for a diverse range of participants, with a simplified submission process of a Solution Summary followed by a Pitch session. A Solution Summary is a 3-page document that addresses how the proposed idea is relevant to the ARPA-H mission and the proposed Women's Health topic areas presented below. The Spark and Launchpad tracks are available for all six Women's Health topics.

2. PROGRAM DESCRIPTION: Spark and Launchpad

For the funding opportunity tracks, the expected period of performance will be 24 months. The selected performers will work directly with a Program Manager (PM) at ARPA-H. They will receive an ARPA-H award contracted through the ARPANET-H Investor Catalyst Hub and the relevant Consortium Management Firm (CMF).

2.1. What is a Spark?

Spark awards will focus on transformative early-stage research efforts aligned with Technology Readiness Levels (TRLs) 1-4 (See description of ARPA-H TRLs) in the specific topics of interest in Women's Health (Section 3). Selected performers will receive an ARPA-H award of approximately \$3M.

2.2. What is the Launchpad?

Launchpad awards aim to accelerate later stage transformative health solutions reaching the public. The Launchpad performers will be at a higher TRL stage (5+) in the specific topics of interest in Women's Health (Section 3) where they still require technical development but are poised to impact health outcomes in the short term. The Launchpad program and funding opportunity will help lower the barriers to successful commercial transition. Launchpad performers will work to mature and grow their businesses through structured education, public and private resources, and domain specific mentorship resources. The Launchpad performers

will receive an ARPA-H award of approximately \$10M and will also work with a contracted Expert-in-Residence (XIR) or Entrepreneur in Residence (EIR) with commercialization and technology transition experience in addition to the PM.

Note: The connection between ARPA-H and an XIR or EIR is established through a Partnership Intermediary Agreement (PIA), where XIRs and EIRs serve as consultants under the intermediary's agreement with ARPA-H.

3. LIST OF TOPICS

This request for solution invites Solution Summary submissions on the following topics of interest in Women’s Health for either the Spark or Launchpad tracks. Please note that submissions outside of topics listed below will not be considered at this time.

- **Women’s Health Topic 01:** Women’s Health at Home
- **Women’s Health Topic 02:** Prioritizing Ovarian Health Through Mid-Life to Prevent Disease
- **Women’s Health Topic 03:** ARTEMIS – Advancing Research Through Enhanced Models for Investigating the Influence of Sex Differences on Health Outcomes
- **Women’s Health Topic 04:** Advancing Women’s Brain Health Via Lymphatic Targeting
- **Women’s Health Topic 05:** Objective and Quantitative Measurement of Chronic Pain in Women
- **Women’s Health Topic 06:** WILD CARD: Revolutionary Breakthroughs in Women’s Health

3.1 Women’s Health Topic 01: Women’s Health at Home

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?

Problem Statement and Opportunity:

Many women are facing considerable barriers to accessing routine preventive healthcare, which is crucial for early detection and management of potential health issues. Primary obstacles include childcare responsibilities, which often prevent women from prioritizing their personal health needs; financial constraints, which can make regular healthcare visits unaffordable; transportation issues, which can make it challenging to reach healthcare facilities; and cultural or family perceptions, which may discourage women from seeking medical attention. There is an urgent need to address these barriers and develop comprehensive strategies and innovative, affordable, and easy-to-use solutions to ensure that all women have access to routine preventive healthcare. Although technologies capable of diagnosing and possibly treating diseases across all ages and stages of a woman’s life within the privacy of one’s own home are increasingly possible, very few are affordable and/or currently available in the marketplace, or are not easy-to-use designed with the customer in mind.

ARPA-H aims to catalyze the development of innovative and impactful platform technologies capable of diagnosing and/or treating women’s health issues in the home environment. Novel platform technologies that monitor, diagnose, administer, treat, or maintain healthy status

across all ages and stages of women's health are of interest. These novel capabilities should empower women to take control of their health and detect and treat disease early, in the privacy of their own home. Successful concepts will improve quality of life by decreasing the complexity and time spent to access healthcare, and measurably improve health outcomes.

Examples of potential capabilities may include, but are not limited to: devices or wearable sensors to assess breast, hormonal, cervical, and pelvic health or diagnose infections (UTIs, STDs); vaginal specimen collection and drug delivery innovations; predicting and preventing premature labor; postpartum and maternal health; mental health and wellness; nutritional support; innovations in telehealth; and healthy microbiomes to support a broad range of women's health topics.

3.2 Women's Health Topic 02: Prioritizing Ovarian Health Through Mid-Life to Prevent Disease

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?

Problem Statement and Opportunity:

Ovarian aging is an ongoing physiological process, culminating in menopause, which signifies the cessation of ovarian function. The ovary has both reproductive and endocrine functions. This topic is focused exclusively on maintaining and enhancing endocrine functions of the ovary through mid-life and beyond. As women age through mid-life and beyond, the decline in estrogen levels that occurs in peri-menopause and menopause results in both short-term and long-term health implications for women. Short-term effects involve hot flashes, night sweats, palpitations, headaches, vaginal discomfort, and urinary issues, while long-term consequences include osteoporosis and a higher risk of cardiovascular and neurological diseases. While Hormone Therapy (HT) is the primary treatment for these symptoms, not all women are candidates for hormone therapies due to their personal or family histories. The lack of solutions that enable simple, timely (continuous or time of need), and cost-effective measurement of hormone levels further exacerbates the challenges of understanding and regulating ovarian, hormone, endocrine, and metabolic health. Further, the optimal time for intervention - which may be decades prior to anticipated decline of ovarian function - is not yet understood.

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 exploration of solutions that promote natural ovarian health beyond mid-life. By prioritizing the development of groundbreaking solutions that improve the ovarian function and overall health through mid- and later stages of a woman's life, we aim to prevent and mitigate diseases and conditions associated with women's aging, ensuring a healthier and extended quality of life.

Examples of promising innovations may include but are not limited to: safe and accessible pharmaceutical interventions to promote ovarian health; understanding ovarian aging in the context of other systems (neuro, osteo, cardio, etc); cell and gene therapies; implantable bioelectronics; and ovarian tissue preservation and reimplantation.

Note 1: The focus of this topic is improvement of ovarian function for endocrine outcomes to prevent acute and chronic disease that follows menopause, thus specifically excluded are topics that address fertility or extended reproductive age.

Note 2: It is also anticipated that this topic will require the development of novel capabilities to non-invasively measure or modulate hormone-or hormone-like substance levels at home to augment and inform the use of treatment interventions. These solutions may be proposed here as a companion to a given intervention, or as stand-alone efforts or under Women's Health at Home topic.

3.3 Women's Health Topic 03: 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?

Problem Statement and Opportunity:

Despite the well-known sex differences between males and females, research often neglects the impact of sex on study outcomes, with a predominant reliance on male animal tissues and cell models in pre-clinical research. This oversight has led to flawed and biased results, particularly affecting women by contributing to safety issues, healthcare disparities, data bias, and inequity, especially in diseases more prevalent in females. The absence of female-specific models poses a significant barrier in understanding female biology and in developing safe and effective drugs and medical devices. The FDA Modernization Act 2.0, enacted in 2023, marks a pivotal shift by endorsing alternatives to traditional animal testing, including *in vitro* and *in silico* models, such as organ-on-a-chip systems and computational approaches. These advancements promise to enhance the development of therapies that are more effective and predictive for women, addressing a critical gap in women's healthcare.

ARPA-H aims to catalyze the development of innovative 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 women-specific models, the platform technology should adequately represent female biology and physiology including the reproductive system, hormonal fluctuations, and genetic and epigenetic differences between males and females. Further proposals could consider how female-and-male-specific behavioral and psychological factors may influence research outcomes, such as stress responses or social behaviors.

Examples of potential capabilities for physical or digital female models may include, but are not limited to:

- Development of customizable "healthy" models that emulate the response of a tissue, organ, or organ system that is critical for women's health over the life course.
- Development of customizable 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.
- Development of models that facilitate an improved understanding of disease heterogeneity based on sex and gender.
- Development of models that include novel features, functions, and design choices that improve the ability to predict the response of women to therapies and interventions.

3.4 Women's Health Topic 04: 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?

Problem Statement and Opportunity:

Neurodegenerative diseases like Alzheimer's Disease (AD), Parkinson's disease, and Multiple Sclerosis (MS) exhibit distinct sex differences in presentation, prevalence or disease course. For example, women represent nearly two-thirds of the 6.7 million Americans living with AD, and they often bear the brunt of caregiver responsibility, leading to significant emotional, physical, and financial impacts. Meningeal lymphatics and glymphatics play a crucial role in maintaining brain health by facilitating waste clearance, regulating immune responses, and supporting brain fluid balance. Impairment of these systems, common in aging individuals, has been linked to various neurodegenerative diseases like AD and MS, as well as major depressive disorder. Despite this, the influence of sex differences in the lymphatic system on brain health has not been extensively investigated as a potential prevention or treatment approach for the millions of women affected by these diseases. There is a pressing need to explore the lymphatic system's potential for the prevention, early detection, and treatment of many neurodegenerative diseases, including AD, Parkinson's Disease, MS, and depressive disorders.

ARPA-H aims to catalyze neurodegenerative disease research by investing in innovative technology that addresses the key challenges in meningeal lymphatics and glymphatic research, diagnosis, treatment, and care. We aim to bring together an interdisciplinary group of researchers, clinicians, and technology experts to accelerate these solutions. All proposed solutions should be developed to ensure fit to the onset, phenotype, and presentation of these disease states in women.

Examples of promising innovations may include, but are not limited to: novel diagnostics leveraging the lymphatic and glymphatic systems' unique functions for disease prediction and monitoring; high-throughput drug studies using advanced discovery methods to identify compounds that penetrate the blood-brain barrier, targeting the lymphatic and glymphatic system to enhance waste clearance; and research focusing on the impact of sex and age on lymphatic vasculature variability, which could shed light on neurodegenerative disease pathology.

Note: Proposers interested in brain health topics that do not specifically include lymphatic system targeting should consider Topic 6: WILD CARD.

3.5 Women's Health Topic 05: Objective and Quantitative Measurement of Chronic Pain in Women

What If Statement: What if women's pain were taken seriously?

Problem Statement and Opportunity:

Women experience pain and pain mitigation differently than men do. There are measurable, sex-based differences in the perception of a variety of pain stimuli, hormone-mediated effects on pain perception, psychosocial effects on pain perception and sex-based differences in

response to opioids. The etiology of these differences is not well understood. Women are also more likely to suffer from chronic pain conditions, rheumatoid arthritis, and migraines. Lack of adequate assessment of women's pain, due in part to gender, racial, and other stereotypes can lead clinicians to underestimate and undertreat women's pain, resulting in prolonged suffering, delayed diagnosis and treatment, and a reluctance to seek medical care. The challenge is exacerbated by the absence of objective, quantitative markers of pain, that do not rely primarily on self-reporting. The lack of biomarkers complicates the stratification of patients and the prediction of disease progression or response to treatment, reducing the success rate of pain treatment clinical trials by nearly 20%. Addressing this, a recent NIH-led workshop highlighted the urgent need for developing and validating objective pain biomarkers to advance pain management and contribute to resolving the opioid crisis.

ARPA-H seeks to 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. These methods should enable clinicians to evaluate disease evolution and to determine how well a patient's course of treatment is addressing their pain. The pain measurement method should be simple, inexpensive and deployable in a range of settings.

Solutions that enable time-resolved, at-home pain monitoring are highly encouraged. While it is acknowledged that a multitude of markers may be needed for a precise and accurate evaluation, it is desired for these markers to be of similar origin (e.g., multiple blood or urine biomarkers, as opposed to MRI exam + genomic screen + blood based biomarkers + urine based biomarkers). The design and intended use of the pain measurement method should consider the psychosocial component of pain and the fact that 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). The solution is intended to quantify and support a patient's claims about their comfort and wellbeing and must agree with self-reported assessments. Methods that accurately identify the location of the pain generator and that distinguish between different pain types are encouraged, as are wearables.

3.6 Women's Health Topic 06: WILD CARD: Revolutionary Breakthroughs in Women's Health

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?

ARPA-H recognizes that some revolutionary advances in women's health may be hindered by the inability to secure public or private sector funding because the concepts are considered too technically challenging, and are not covered in the topics above. In the WILD CARD topic, we seek to catalyze breakthroughs that will transform the paradigm of women's health, acknowledging the critical gaps in data, the historical underrepresentation in clinical trials, and the lack of focused research on the unique health needs of women throughout their lives. By advocating for innovative solutions that transcend mere data collection, ARPA-H aims to revolutionize the methodologies for data generation, analysis, and application in women's health. We invite proposals that employ cutting-edge research, novel technologies, new business models to sustain investment, and interdisciplinary approaches to forge personalized and effective strategies, addressing the comprehensive and specific health challenges women face. This topic is dedicated to reshaping women's health research into a more comprehensive, inclusive, and forward-thinking endeavor, ensuring significant improvements in global health outcomes for women. If successful, the concepts pursued under this topic will change the

conversation - and more importantly the practice - of how we engage women's health day-to-day.

Specifically excluded from this topic are iterative and standard approaches, including traditional clinical trials and work that is already well-supported by other private and public funds, or is otherwise specifically described and solicited in Sprint Topics 1-5.

4. EVALUATION METHOD

This Request for Solutions (RFS) is a competitive solicitation seeking solutions for innovative technologies that address the topic areas under Section 3. The government will evaluate all Solution Summaries and Pitches against the evaluation criteria stated in this RFS Section 4.2. Each Solution Summary and Pitch will be evaluated on its own merit. **ARPA-H is under no obligation to respond to every submission, proceed with any Solution Summaries/Pitch, or select any specific number of Solution Summaries/Pitch in each topic.** ARPA-H may also elect to fund several or none of the proposed approaches to a given topic. Proposed approaches of merit, but not selected for funding may be placed in the "Submissions Library," as outlined in Section 4.1.4 of this RFS. During the evaluation process, submissions may be handled by support contractors for administrative purposes and/or to assist with technical evaluation. All support contractors performing this role are expressly prohibited from performing ARPA-H-sponsored technical research and are bound by appropriate non-disclosure agreements (NDAs).

4.1 Evaluation Process

4.1.1 Solution Summary

ARPA-H will review the submitted Solution Summary based on the evaluation criteria stated in this RFS Section 4.2. The Solution Summaries must clearly align to the RFS topics (Section 3) and comply with all requirements detailed in this RFS. A subset of submissions will be invited for a subsequent in-person pitch session. An ARPA-H PM (which is a federal employee) will be the sole evaluator/decider for each Solution Summary but may rely on additional insights from ARPA-H contracted XIR/EIR, support contractors, or systems engineering and technical advisory (SETA) contractors. **Due to expected volume of submissions, proposers will only be notified about whether they advance to the Pitch phase, do not advance to the Pitch phase, or are placed in the Submissions Library (in accordance with Section 4.1.4). Proposers WILL NOT RECEIVE TECHNICAL FEEDBACK on their individual submission.**

ARPA-H reserves the right to limit the number of proposers invited to pitch. As such, a proposer's Solution Summary may be evaluated to be of merit, but not invited to pitch and subsequently placed into the "Submissions Library," as outlined in Section 4.1.4 of this RFS.

4.1.2 Pitch

During the in-person pitch sessions, the proposing team will present their ideas to the ARPA-H team in a slide deck format, with a Question and Answer (Q&A) session following the pitch. The in-person pitch sessions will allow ARPA-H to evaluate the submissions quickly and efficiently. As

needed, ARPA-H reserves the right to ask pitch participants for additional information. ARPA-H will review the pitches based on the evaluation criteria below. An ARPA-H PM (which is a federal employee) will be the sole evaluator/decider for each pitch but may rely on additional insights from ARPA-H contracted XIR/EIR, support contractors, SETA contractors, or other subject matter experts. **Due to the expected volume of submissions, proposers will be notified about whether they advance to Invitation for Collaboration & Negotiation (IC&N), do not advance to IC&N, or are placed in the Submissions Library (in accordance with Section 4.1.4). Proposers WILL NOT RECEIVE TECHNICAL FEEDBACK on their individual submission.**

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. As such, a proposer's Pitch may be evaluated to be of merit, but not invited to IC&N and subsequently placed into the "Submissions Library," as outlined in Section 4.1.4 of this RFS.

Note: Templates will be provided to those selected for the Pitch Phase.

4.1.3 Invitation for Collaboration & Negotiation (IC&N)

After evaluating all the pitches, the ARPA-H team will select a subset of proposers to proceed to the IC&N Phase. Proposers will be notified after their pitch if they are selected or not selected to move onto IC&N. ARPA-H reserves the right to limit the number of proposers invited to IC&N. Those not invited to IC&N Phase will be notified via email.

The first step in IC&N is Technical Collaboration. The selected proposers will work with the PMs to collaboratively develop the following items:

1. Scope of Work (SOW)
2. Technical Milestones
3. Project Timeline (or Period of Performance)
4. If Applicable - Government Furnished Property (GFP) / Government Furnished Information (GFI)

The second step in IC&N is negotiation of the following documents:

1. SOW (to include milestones, timeline, GFP/GFI)
2. Intellectual Property
3. Costs
4. Pricing structure

The Government will not pay proposers for costs associated with IC&N (e.g., proposal development, negotiations), unless otherwise stipulated.

After the IC&N Phase an award will be issued to the selected proposer. Awards will be made in the form of Technical Direction Letters (TDLs) from the Agreements Officer (AO) to the Investor Catalyst (IC) Hub CMF. The TDL triggers the CMF to issue a subaward to the selected proposer. Each TDL will incorporate the collaborative SOW (e.g., milestones, timeline, GFP/GFI, IP, costs) and all TDLs will be governed by the CMF's Base OT Agreement, unless otherwise noted in the AOI.

Note 1: Templates will be provided to those selected for IC&N.

Note 2: It is not required to have a www.SAM.gov Unique Entity Identifier (UEI) or CAGE Code to apply, however, to be eligible for a TDL, proposers are required to have an UEI and be registered in www.SAM.gov.

4.1.4 Submissions Library

The Submissions *Library* is the repository of Selectable submissions available for future selection. Only Consortium Members who are approved spokes may have their submissions placed into the Library. Proposers that are evaluated as “Selectable” but not invited to Pitch (or IC&N) will be placed in the *Submissions Library*. This *Library* will be maintained by the CMF, through coordination with the cognizant AO and Agreement Specialist (AS). Proposer’s submissions that are placed in the *Library* will be valid for 18 months from date of submission.

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

4.2 Evaluation Criteria

ARPA-H will use the below evaluation criteria to evaluate the Solution Summaries and Pitches. Even if the submission is deemed Selectable, ARPA-H reserves the right to not invite the proposer to the next phase and placing them in the Submissions Library.

If an organizational conflict of interest (OCI) presents itself during the Evaluation, ARPA-H will assess the OCI and decide if the potential OCI can be avoided or mitigated. If a potential OCI cannot be avoided or mitigated, ARPA-H will remove the proposer from further consideration. All support contractors (e.g., XIR/EIR, SETA, etc.) supporting ARPA-H are expressly prohibited from performing ARPA-H-sponsored technical research and are bound by appropriate non-disclosure agreements (NDAs).

4.2.1 Solution Summary Evaluation Criteria

ARPA-H will review all conforming Solution Summaries and make an overall determination of “selectable”, “not selectable”, or “Submissions Library” based on the following criteria.

1. Relevancy to the proposed topic area in Women’s Health
2. Technical Merit, which is based on how the Solution Summary addresses the following Heilmeyer Questions (HQ):
 - HQ #1: What health problem are you trying to solve?
 - HQ #2: How is it done today, and what are the limits of current practice?
 - HQ #3: What is new in your approach and why do you think it will be successful?
 - HQ #4: Who cares? If you succeed, what difference will it make? What Health Outcomes are you accelerating?
3. **FOR LAUNCHPAD ONLY:** Commercial viability - the proposed solution shows promise of commercial viability

ARPA-H is anticipating receiving more Solution Summaries than has resources to award. All submissions will be fairly evaluated. The government reserves the right to limit the number of

proposers invited to pitch. As such, a proposer’s solution may be determined selectable, but not invited to pitch. Solution Summaries that are selected for the Pitch Phase will be notified in writing as soon as practicable.

4.2.2 Pitch Evaluation Criteria

SPARKS ONLY: Evaluation for Spark Pitches will be based on an integrated assessment of the following criteria: Technical Merit, Team, and Price. **LAUNCHPAD ONLY:** Evaluation for Launchpad Pitches will be based on an integrated assessment of the following criteria: Technical Merit, Team, Price, User Experience, and Commercial Viability.

For both Sparks and Launchpad Pitch submissions, technical merit takes precedence in the evaluation process and will be assessed first. Pitches lacking technical merit will not be evaluated further and determined “Not Selectable.” Pitches with technical merit will reviewed based on the following criteria.

The below technical criteria will be considered in the evaluation of the Pitches to determine whether or not a Pitch is “selectable”, “non-selectable”, or placed in the “Submissions Library”:

1. **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 and address the following HQs:
 - HQ #1: What health problem are you trying to solve?
 - HQ #2: How is it done today, and what are the limits of current practice?
 - HQ #3: What is new in your approach and why do you think it will be successful?
 - HQ #4: Who cares? If you succeed, what difference will it make? What Health Outcomes are you accelerating?
 - HQ #5: What are the risks?
 - HQ #6: How long will the program take?
 - HQ #8: What are the mid-term and final exams to check for success?
 - HQ #9: To ensure equitable access to all people, how will cost, accessibility, and user experience be addressed?
 - HQ #10: How might this program be misperceived or misused (and how can you prevent that from happening)?

2. **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.

3. **Price:** 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) and HQ #7. For the IC&N Phase: ARPA-H will evaluate pricing for reasonableness.

- HQ #7: How much will the program cost?

- 4. FOR LAUNCHPAD ONLY - 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?
- 5. FOR LAUNCHPAD ONLY - 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.

5. SUBMISSION INSTRUCTIONS

It is important to read and follow the "Solution Summary" preparation instructions carefully, which are outlined below. Pay special attention to the requirements concerning Human Subjects and use of Vertebrate Animals if your project encompasses either item (see Human Subjects and Animal Subjects Research).

If invited to Pitch, proposers must apply to become an Investor Catalyst (IC) Hub Spoke, if they haven't already. If selected for award, proposers must have their spoke approval and UEI to receive award.

Solution Summaries will be submitted through the BIDS portal where Advanced Technology International (ATI) serves as the BIDS system administrator. All proprietary submission information will be protected. A proposer's submission under this RFS indicates concurrence with the aforementioned responsibilities.

The Team Lead may only submit one Solution Summary per topic but can submit to all topics. The Team can be any mix of institutions/organizations and can be part of multiple Solution Summaries.

Salary Limitation: ARPA-H is subject to the Health and Human Services (HHS) appropriations act, as a result ARPA-H may not use appropriated funds to pay the direct salary of any individual above the Federal Executive Schedule Level II salary (see the salaries and wages pay tables on www.opm.gov for Federal Executive Schedule salary levels).

For purposes of the salary limitation, the terms "direct salary," "salary," and "institutional base salary," have the same meaning and are collectively referred to as "direct salary". An individual's direct salary is the annual compensation for their direct effort (costs) under the IC Hub Agreement. Direct salary excludes any income that an individual may be permitted to earn outside of the IC Hub Agreement. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative costs). The salary rate limitation does not restrict the salary that an organization (i.e., VentureWell) may pay an individual working under an ARPA-H agreement; it merely limits the portion of that salary that may be paid with appropriated funds.

The salary rate limitation applies to all subawards, subcontracts, and subagreements.

Note: *The prime performer can propose Government Entities as a sub performer only if they provide a statement from the Government Entity's direct supervisor or agency ethics attorney, stating the individual(s) have no ethical challenges receiving compensation for their services as a Federal employee and have no Conflicts of Interest to support the prime performer. If a Government entity is interested in working directly with the Government team supporting this program, please contact the Womenshealth@arpa-h.gov.*

5.1 BASIC INFORMATION:

The following information fields are required for a successful submission:

Cover Page (does not count against page limit)

- Solution Summary Title:
- Topic Area #:
- Organization Name:
- Organization Address:
- Organization's UEI:
- 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 competencies¹ and Levels of effort².
- 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):

Note 1: Non-U.S. entities may participate to the extent that such participants comply with any necessary nondisclosure agreements, security regulations, export control laws, and other governing statutes applicable under the circumstances. However, Non-US entities are encouraged to collaborate with domestic U.S. entities. In no case will awards be made to entities organized under the laws of a covered foreign country (as defined in section 119C of the National Security Act of 1947 (50 U.S.C. § 3059)) or entities suspended or debarred from business with the Government.

¹ A core competency is a particular set of skills, knowledge, abilities, and resources that collectively distinguish the team and enable it to excel in its specific area of pursuit.

² Level of effort for individual team members refers to the amount of time and resources that each member invests in carrying out their responsibilities for the proposed effort.

5.2 SOLUTION SUMMARY:

A 3-page Solution Summary, using minimum 11-point font and minimum 0.5” margins on all sides, should be submitted in a PDF format to ARPA-H Sprint for Women’s Health Website, listed on the RFS cover page (see Solution Summary Template for more details). Attachments and embedded links shall not be included. ARPA-H recommends figures and data only to convey key points, as the proposer only has three pages for their solution summary.

The Solution Summary should address why the proposed idea is relevant to the proposed topic areas in women’s health. This Solution Summary also should demonstrate the technical merit by addressing the first four Heilmeier Questions (HQs) (HQ’s can be found here: [link](#)). Proposers should frame their responses using the following items:

- HQ #1: What health problem are you trying to solve? Articulate your objectives using absolutely no jargon.
- HQ #2: How is it done today, and what are the limits of current practice?
- HQ #3: What is new in your approach and why do you think it will be successful?
- HQ #4: Who cares? If you succeed, what difference will it make? What Health Outcomes are you accelerating?

FOR LAUNCHPAD ONLY: the Solution Summary should address how the proposed idea has the promise of Commercial Viability.

Note 1: ARPA-H programs are guided by answering the HQs. Please see this [link](#) on ARPA-H website for a list and detailed explanation of Heilmeier Questions. The first four bullet points above represent the first four HQs, which should be answered in the Solution Summary. Those proposers invited for pitch, should answer all HQs during their pitch presentation.

Note 2: Any references can be added as an appendix and will not count towards 3-page maximum.

Note 3: Further instructions for the Pitch Phase and IC&N Phase will be provided to proposers once selected.

Key Dates:

Item	Date*	Time
Draft Request for Solutions (RFS) posted	Friday, March 1, 2024	
Solution Summary Phase		
Proposer's Day	Wednesday, March 6, 2024	
Final RFS posted	Wednesday, March 13, 2024	
Questions Deadline	Wednesday, March 27, 2024	5:00 PM
Solution Summary Deadline	Monday, April 15, 2024	12:00 PM
Pitch Phase		
	May - July 2024	
Invitation for Collaboration & Negotiation (IC&N)		
	July - Aug 2024	
Award		
	September 2024	

**Note dates are notional and dependent on the number of submissions received*