

ARPA-H Sprint for Women's Health Frequently Asked Questions (FAQs)

Late Updated: March 12th, 2024 Note: This document is subject to change

Solution Summary Phase

Q: What is the overall goal of the Sprint for Women's Health?

A: The Advanced Research Projects Agency for Health (ARPA-H) Sprint for Women's Health intends to fundamentally change the trajectory of women's health care research and radically accelerate the next generation of discoveries. Learn more here: <u>https://sprint.investorcatalysthub.org/request-for-solutions/</u>.

Q: Are there priority research areas?

A: The RFS invites Solution Summary submissions on six topics of interest in women's health for either the Spark or Launchpad track. Please note that submissions outside of topics listed below will not be considered at this time. Learn more about the topic areas here: <u>https://sprint.investorcatalysthub.org/request-for-solutions/</u>.

Q: How were the topic areas selected?

A: ARPA-H Program Managers developed topic areas informed by an ARPA-H executive convening and problem formulation process on women's health.

Q: What if I have an idea that doesn't fit into the topic areas?

A: If your idea doesn't fit into Topic 1-5, submit to Topic 6: WILD CARD: Revolutionary Breakthroughs in Women's Health.

Q: Do we have to declare if we are applying for Spark or Launchpad?

A: Yes. You will be required to select Spark or Launchpad for your topic area in your Solution Summary submission.

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Q: Are solutions focused on diagnostics, therapeutics, generative AI, and/or care delivery models eligible?

A: Yes please refer to the topic description for further information. 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.

Q: Will there be prioritization for solutions 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.

Q: Can ARPA-H map development milestones to the Technology Readiness Levels (TRL) to help us determine if we should apply to Spark or Launchpad?

A: ARPA-H will not map development milestones. Please refer to the TRL document <u>here</u>. It is up to the proposers to determine if they should apply to Spark or Launchpad track.

Q: Where do animal models fit into the Technology Readiness Levels (TRL)?

A: Please refer to the TRL document <u>here</u>. It is up to the proposers where they believe they should use animal models within their proposed solution.

Q: Where do clinical trials fit into the Technology Readiness Levels (TRL)?

A: Please refer to the TRL document <u>here</u>. It is up to the proposers where they believe they should use clinical trials within their proposed solution.

Q: Does a Launchpad solution need to be market-ready in a certain period of time to receive funding?

A: Launchpad awards aim to accelerate later stage transformative health solutions reaching the public. The Launchpad performers will be at a higher Technology Readiness Level (TRL) stage (5+) in the specific topics of interest in Women's Health where they still require technical development but are poised to impact health outcomes in the short term.

Q: Our solution seeks to apply technology in a novel way. Are implementation solutions eligible for funding?

A: Yes.



Q: In past Proposer's Days there have been defined key performance indicators and deliverables, which helped to determine project scope and budget. What are the expected key performance indicators and deliverables for each funding track?

A: Please refer to each topic to determine what will be the key performance indicators. During pitch phase the proposer will provide a more in depth approach to key performance indicators and deliverables for each funding track and topic.

Q: What is your preferred format for the Solutions Summary? Can you include figures and data? Can we include citations and do they count towards the page limit?

A: ARPA-H will provide a template to use for the Solutions Summary. This is currently in a word doc format but when submitting you are REQUIRED to turn this into a PDF. Please use figures and data only to convey key points, as the proposer only has three pages for their solution summary. Link to Solution Summary template to be provided when available.

Q: What is your preferred format for the budget request (i.e., Rough Order of Magnitude (ROM))?

A: ARPA-H will provide a template to use for the ROM. Link to ROM template to be provided when available.

Q: Can we/do we need to include letters of support in the Solutions Summary application submission?

A: Letters of support are not required.

Q: Does the "Pricing" Evaluation Criteria refer to the project cost or the solution cost?

A: The "Pricing" Evaluation Criteria refers to the 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).

Q: Can I meet with ARPA-H and/or an ARPA-H PM to discuss our proposed team and solution prior to submission?

A: No, we will not provide feedback on solution summaries or pitches prior to submission.

Pitch Phase

Q: When will applicants be informed that they have made it to the pitch phase?

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A: Following the solution summary evaluation phase applicants will be informed. The pitch phase will take place between May - July 2024.

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 \$100M in awards. We do not have a defined number of awards by funding track or topic area.

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

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

Q: Do I have to be a member of SAM.gov to be eligible to apply? Do I need to have a Unique Entity Identifier (UEI) when applying?

A: No, it is not required to have a SAM.gov Unique Entity Identifier (UEI) to apply, however, to be eligible for AWARD proposers are required to have an UEI and be registered in SAM.gov.

Q: Do I need a CAGE number to apply?

A: No, it is not required to have a CAGE number to apply, however, to be eligible for AWARD proposers are required to have CAGE Code

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. You do not have to be a US-based company.

Q: Are non-profit organizations, for-profit organizations, government agencies (e.g., state health department), and start-ups eligible to apply?

A: Non-profit organizations, for-profit organizations, and start-ups are eligible to apply. Government Agencies are not eligible.

Q: Am I able to apply to the multiple government funding opportunities for my solution (e.g., ARPA-H's Open BAA and and Sprint for Women's Health)?

A: Yes.



Q: Am I eligible to receive funding if I already receive other government funding (e.g., NIH) for my solution?

A: Yes. 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.

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

A: Yes. 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 to receive award. You can apply to be an Investor Catalyst Hub member here: <u>https://investorcatalysthub.org/spoke-network/</u>.

Q: Will early submissions be prioritized?

A: No, all submissions will be reviewed after the submission deadline.

Q: Will any priority be given for women owned, veteran owned, or service-disabled veteran owned, or other minority owned companies?

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.

Q: Do the Spark or Launchpad budget and awards include and cover direct and indirect costs?

A: Direct and indirect costs should be included in all pricing supporting the Women's Health Initiative.

Q: What is the solutions library? Are the solutions in the solutions library publicly available?

A: The solutions library is a confidential library ARPANET-H will maintain with the submittals of promising applicants to speed up the review and approval for additional future funding. It is not publicly available.

Q: When is the deadline for submissions?

A: All submissions must be completed before Monday, April 15th at 12pm ET.

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Q: If awarded, what is the contract timeline for each funding track?

A: Awards are anticipated by the end of the Government Fiscal Year (September 30, 2024).

Q: If awarded, is there expectation that the awardee will match a percent of the funding received?

A: While there is no requirement for cost-share, proposers are reminded Sparks are capped at \$3M and Launchpads are capped at \$10M.

Q: If awarded, how are payments made and what is the payment cycle? Do awardees need to be able to cover upfront costs?

A: Each awarded project will have a negotiated Milestone Payment schedule.

Q: If awarded, are their salary caps? If so, what is the salary allowance for the project lead during the project time frame?

A: Yes, there is a Salary Cap, the RFS will be updated to incorporate the Salary Cap.

Q: If awarded, does this funding qualify as R&D that must be amortized over five years?

A: ARPA-H will not dictate this as it is applicable to the business dealings of each proposer.

Q: If awarded, how is intellectual property (IP) impacted? Will the NIH have ownership or rights to any of the research that is funded through ARPA-H?

A: ARPA-H intends to negotiate the requisite IP rights prior to each award.

Teaming

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, it is your responsibility to reach out to other organizations you are interested in teaming with. Prospective performers are encouraged (but not required) to form teams with varied technical expertise to submit a Solution Summary to the Sprint. To facilitate this process, we have created a <u>teaming page</u> where prospective performers can share their profiles and learn more about other interested parties.

Q: Will you facilitate a request for collaboration with public health departments?

A: No, it is your responsibility to reach out to other organizations you are interested in teaming with. Prospective performers are encouraged (but not required) to form teams with varied technical expertise to submit a Solution Summary to the Sprint. To facilitate this process, we have created a <u>teaming page</u> where prospective performers can share their profiles and learn more about other interested parties.

Q: Can the same proposer or proposer 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.

Q: Can an organization join the Investor Catalyst Hub to support solutions even if we do not plan to submit our own solutions?

A: Yes, we invite you to apply to be an Investor Catalyst Hub member here: <u>https://investorcatalysthub.org/spoke-network/</u>.