

Request for Information: Accelerating and Incentivizing Innovation through ARPA-H and FDA Collaboration

OVERVIEW

The Advanced Research Projects Agency for Health (ARPA-H) is seeking unique and creative ideas on how to productively engage with the Food and Drug Administration to encourage and incentivize public-private partnerships in the health ecosystem, with the goal of accelerating better health outcomes for everyone.

In March 2022, ARPA-H was launched to take on ambitious research and development (R&D) projects to accelerate better health outcomes for everyone. To fulfill this mission, ARPA-H will work with patients, healthcare providers, our federal and non-federal stakeholders, and our performers to both conduct programs and transition resulting products and technologies. The most transformative solutions may benefit from bold new regulatory strategies that can encourage innovation and accelerate impact, without compromising patient safety.

ARPA-H is establishing a strong collaborative relationship with the FDA to help facilitate successful development and transition of health innovations developed by ARPA-H performers into safe and effective solutions. ARPA-H has the authority to partner with the FDA to discuss, confidentially as needed (section 499A of the Public Health Service Act, 42 U.S.C. 290c), the development status of medical products and projects that are a high priority to ARPA-H. FDA and ARPA-H are working together to address pre-competitive challenges that might help an emerging area, as well as pathways and services for performers to accelerate the impact of their solutions.

Further, ARPA-H can play a unique role as a funder in the health ecosystem to create novel incentives for ARPA-H performers to promote public-private partnerships. ARPA-H can also complement performer-facing incentives with its unique statutory authority to financially reimburse FDA for activities to support ARPA-H priorities (section 499A of the Public Health Service Act, 42 U.S.C. 290c). ARPA-H and FDA collaboration will inform the development of these approaches to promote health innovation.

This Request for Information seeks novel insights, ideas, incentives, approaches, and models at the development stage and during pre-submission, submission, and post-submission interactions to help promote and accelerate innovation while prioritizing patient safety to yield better health outcomes. The purpose of this effort is to understand the art of the possible under the current regulatory and statutory paradigm. The purpose is NOT to propose any changes to FDA

regulatory authority or statutes. Respondents shall propose specific practices that the US Government might adopt to speed approvals and support emerging health innovations. Specifically, we are requesting any of the following from respondents:

- New and innovative models to accelerate pre-competitive development of platform technologies to support downstream development of products resulting from those platform approaches in a disease agnostic manner.
- Proposed applications of ARPA-H's unique authority to reimburse FDA activities to support ARPA-H's priorities related to emerging areas or pathbreaking innovations, creating novel incentives, and helping ensure delivery of solutions to the patients and healthcare providers that need it most.
- Strategies to accelerate alternatives to traditional human or animal research for medical product development.
- Strategies to use real-world evidence (RWE) and other post-market surveillance methodologies to understand gaps in care and how to ubiquitously scale novel therapies to all populations
- Case studies on the development of innovative technologies that highlight best practices for using existing FDA regulatory pathways.
- Case studies that highlight specific opportunities for R&D innovation supported by ARPA-H to enhance or accelerate use of existing FDA regulatory pathways for novel or transformative medical products.
- Proposed models for how ARPA-H could best support its performers on regulatory topics to make their solutions measurably safer and more effective while facilitating path to market (e.g., through funding specific line items or offering services through our Project Acceleration and Transition Innovation Office ([PATIO](#))).

DATES:

Interested persons and organizations are invited to submit comments on or before 5 p.m. ET on May 30, 2023. Early submissions are encouraged as materials will be reviewed on a rolling basis.

ADDRESSES:

Interested individuals and organizations should submit comments electronically to FDACollaboration@arpa-h.gov and include "RFI Response: Accelerating Innovation through ARPA-H and FDA Collaboration" in the subject line of the email. Questions on the RFI can also be sent to this address including "RFI Question" in the subject line of the email. Due to time constraints, mailed paper submissions will not be accepted, and electronic submissions received after the deadline may not be taken into consideration.

INSTRUCTIONS:

Response to this RFI is voluntary. Respondents may address as many or as few topics as they wish. Each individual or institution is requested to submit only one response. Responses to this RFI may be viewed by Government and support contractors. The Government will review responses for market research purposes only. The Government does not intend to provide a response to submissions for this RFI. The Government will not provide reimbursement for any costs incurred in responding to this RFI. ARPA-H is not seeking proposals or applications for financial assistance in response to this RFI, and submissions cannot be accepted to form binding legal agreements of any type.

Electronic responses must be provided as attachments to an email rather than a link. Comments of five pages or fewer (2,500 words) are requested; longer responses will not be considered. Responses should include the name of the person(s) or organization(s) filing the response. Responses containing references, studies, research, and other empirical data that are not widely published should include electronic links to the referenced materials.

Any information obtained from this RFI is intended to be used by the Government on a non-attribution basis for planning and strategy development. ARPA-H will not respond to individual submissions. A response to this RFI will not be viewed as a binding commitment to develop or pursue the project or ideas discussed. Comments submitted in response to this notice are subject to the Freedom of Information Act (FOIA). Any proprietary information shall be clearly marked in the document.