Special Notice (SN) ARPA-H-SN-25-124
Proposers' Day Announcement for Advanced Research Projects Agency for Health (ARPA-H)/Proactive Health Office (PHO)
Opportunity: Rare disease AI/ML for Precision Integrated Diagnostics (RAPID)

I. KEY INFORMATION

Proposers' Day	January 23, 2025: 8:30AM to 4:00PM PST
Location	San Francisco, CA and Virtual
Website for Registration	Proposers' Day Registration
Registration Opens	December 19, 2024
Registration Closes	January 21, 2025, at 12:00PM ET or when capacity is reached, whichever comes first.
Technical Point of Contact	Scott Gorman, Program Manager, ARPA-H / PHO Office
Program Email	RAPID@ARPA-H.gov
Program Solicitation	ARPA-H-SOL-25-119 (DRAFT Anticipated in December 2024)

II. INTRODUCTION

This Special Notice is intended to alert the scientific community to a newly approved ARPA-H Program and notify potential proposers of an associated Proposers' Day (PD). Under the cognizance of PHO, ARPA-H intends to release a DRAFT Innovative Solutions Opening (ISO) for the RAPID Program in early January 2025 (ARPA-H-SOL-25-119) in SAM.gov.

Potential proposers are encouraged to attend the optional RAPID PD. While not mandatory, ARPA-H is hosting the RAPID PD to achieve the following:

- Provide information about the RAPID Program, including its goals, scope, timeline, and the forthcoming ISO.
- Provide a venue to facilitate teaming and collaboration opportunities among potential proposers. Note: ARPA-H anticipates teaming will be required to accomplish the RAPID program goals.

Attendance at this event is not a requirement for submission of Solution Summaries or Proposals in response to the RAPID ISO.

ARPA-H will collect participant questions throughout the event and publish answers on the RAPID Program page. PD slides and a recording of the event will be made available on the RAPID Program page and on SAM.gov.

RAPID Proposers' Day will be a hybrid (in-person and virtual) event. Advance Registration is required. Registration requests will only be accepted from the potential proposer community, and at the discretion of ARPA-H. Registration does not guarantee acceptance to attend. Accepted attendees will be notified via email and will also be provided further details about the event at that time. Proposers' Day Participation is not intended for patients, patient advocates, press, or a general interest audience.

Patient organizations interested in collaborating with RAPID are invited to join an informational event to be held February 25, 2025. We expect to provide funding to several patient advocacy groups to support RAPID activities and ensure patient perspectives are integrated throughout the program. A separate Special Notice will be forthcoming. To register for the Patients' Day event, please visit the RAPID program page: https://arpa-h.gov/research-and-funding/programs/rapid

III. RAPID – PROGRAM INFORMATION

The following is a brief description of the RAPID Program. Full programmatic details will be provided in the ISO.

RAPID – What if we could end the rare disease diagnostic odyssey?

RAPID aims to end the prolonged diagnostic odysseys affecting millions of rare disease patients worldwide. RAPID is designed to accelerate the development of novel diagnostic support tools for population-scale rare disease detection, systematically identifying and diagnosing rare disease patients efficiently and accurately. By aggregating and harmonizing fragmented data and employing advanced AI/ML techniques, RAPID aims to drive the development and deployment of comprehensive and highly accurate rare disease detection models.

The program aims to democratize access to advanced diagnostic support tools, ensuring that underserved and marginalized communities benefit from these innovations. By prospectively validating models in diverse clinical settings, RAPID seeks to transform the landscape of rare disease diagnosis, enabling timely and effective care for millions of patients.

While the primary goal of RAPID is to aid clinical diagnosis for rare diseases, the program is also expected to uncover new disease insights and biomarkers, support drug development, and impact the broader healthcare ecosystem.

Technical Approach

The RAPID program aims to systematically identify undiagnosed rare disease patients at scale, leveraging novel training data, AI/ML, and real-world validation. The program will be conducted over two consecutive phases. Initially, ARPA-H plans to solicit innovative solutions for Phase I and Phase II that address the following Technical Areas (TAs): TA1, TA2, and TA3. A subsequent solicitation for TA4 will be issued separately at a later date. TA4 performers will only participate in Phase II. An Independent Verification and Validation (IV&V) partner will be selected separately from the RAPID ISO and will provide continuous support and oversight throughout the program.

1. **TA1 – Massive-Scale Rare Disease Dataset:** Develop the largest curated dataset of longitudinal rare disease patient health data by integrating information from a fragmented data landscape. This extensive resource, spanning thousands of rare and ultra-rare diseases, is purpose-built to accelerate the development and validation of advanced detection algorithms and diagnostic tools. Sustainable systems will ensure the continuous aggregation and curation of patient data, driving transformative advancements in rare disease detection and diagnosis.
2. **TA2 - Novel Diagnostic Indicators and Population-Scale Discovery:** Leverage cost-effective, widely accessible, and remotely deployable digital tools to collect data directly from patients, creating a comprehensive, multimodal dataset of rare disease patient health information. This dataset is designed to drive the discovery of novel diagnostic indicators and enable scalable detection of rare diseases in previously undiagnosed individuals, with an emphasis on reaching underrepresented and underserved populations.
3. **TA3 – Sustainable Platform for AI Diagnostic Development:** Establish an enduring Rare Disease Data Commons with a benchmark dataset, enabling the accelerated development and empirical evaluation of rare disease diagnostic models. This dynamic, AI/ML-optimized platform will support interoperable data collection, sharing, analysis, and evaluation among key

stakeholders, driving advancements in diagnostic decision support systems for rare diseases.

4. **Model Benchmarking:** Following the initial phases of data collection and platform development, the RAPID Program will initiate a benchmarking effort to empirically evaluate rare disease detection models. The ARPA-H IV&V partner will facilitate the benchmarking process and collaborate with performers to integrate benchmarking tools, methodologies, and evaluation results into the TA3-developed platform. These results will provide critical insights to guide the selection of TA4 performers for Phase II.

Program Structure

RAPID is a 4.5 year (54-month), two-phase program with a 21-month Phase I period and an option for a 33-month Phase II period. Multiple awards are anticipated. Data collection and processing will begin in Phase I and continue through Phase II. For TA1, TA2, and TA3 the option to advance to Phase II may be exercised, at the Government's sole discretion, based on technical progress measured against metrics and milestones defined in the Innovative Solutions Opening (ISO), and based on funding availability. A reduced number of Phase I performers are expected to receive funding to advance to Phase II.

In year two of the program, a Phase II solicitation will be released to select TA4 performers. TA4 performers will leverage data and infrastructure from TA1-3 to develop, deploy, and validate novel rare disease detection systems in both clinical and direct-to-patient settings, with real-world performance assessed through prospective validation.

Phase I (months 0-21): Data Aggregation and Infrastructure Development

In Phase I, TA1 and TA2 performers will initiate data aggregation and collection efforts. TA2 performers will also design, test, and deploy scalable approaches for collecting multimodal data directly from patients. By the end of Phase I, TA1 and TA2 performers are expected to submit validated data that meets all requirements (as detailed by the ISO) and is fully prepared to support benchmarking and algorithm development for TA4 performers. Initially, TA3 performers will prioritize the development of platform functionalities for processing data, as well as creating, maintaining, and hosting the Rare Disease Benchmark Dataset. Once baseline capabilities are established, TA3 performers will shift their efforts toward enabling the benchmarking of machine learning models.

Phase II (months 22-54): Development, Deployment, and Validation

During Phase II, TA1 and TA2 performers will build upon their initial efforts, with an expanded focus on scaling to address ultra-rare conditions and incorporating international data sources. TA3 performers will prioritize the continuous enhancement of core platform capabilities while advancing functionalities for real-time data exchange and collaboration with data providers, deploying models in clinical settings, and facilitating external model evaluation.

It is expected that TA4, solicited at a later date, will be incorporated during Phase II. TA4 model development will follow an iterative process, involving continuous cycles of development, testing, and refinement, with prospective validation conducted across diverse real-world settings to ensure effectiveness and applicability.

IV: RAPID – PROPOSERS' DAY INFORMATION

Proposers' Day Structure

The RAPID Proposers' Day will be a one-day event. It will be hosted in-person in San Francisco, California and virtually via Zoom. The RAPID Proposers' Day will include presentations by ARPA-H, including technical overview of the RAPID Program, scope, timeline, the upcoming ISO, and the use of Other Transaction (OT) Agreements. This event will provide a venue for potential proposers to network and consider collaboration opportunities. Additionally, the Proposers' Day will host a limited number of lightning talks. Please review the individual event element sections below for more information.

Lightning Talks

During registration, attendees should indicate their interest to present a lightning talk during Proposers' Day. This is an opportunity for performers to showcase their ability with the intention of forming the best teams with other performers at the meeting. This talk will not be a part of the proposal selection process and is not required, particularly for those who have already identified teams. The lightning talks are limited to a maximum of (5) minutes and accompanied by a slide presentation. Lightning talks will be accepted on a first-come first-served basis, and will require advanced registration on the RAPID registration site. Accepted attendees will be provided instructions on how to submit their lightning talk slides, which must be shared with ARPA-H before registration closes.

Posters

Proposer's Day will include an optional poster session designed to facilitate collaboration and team formation. Interested attendees and/or proposers are invited, but not required, to request space for one poster per team that summarizes the research interests and/or technical capabilities related to the TA(s) the team plans to propose. Posters should measure no larger than 3.75 ft x 3.75 ft, and landscape layout is preferred. Presenters must provide their own poster stand. Presenters will have time allocated to stand by the poster, present their work and answer questions from interested parties. Posters will not be evaluated by the government team and do not contribute towards the government's future evaluation of any submitted solution summary or proposal. Posters will be accepted on a first-come, first-served basis, until the maximum possible number of submissions given the space constraint for the PD is reached, considering relevance and diversity of presenters. Interested attendees must identify their intention to present a poster during registration. Poster presentations are restricted to those attending the meeting in-person.

Teaming Profiles

Interested parties are also encouraged to submit a 'teaming profile' as part of their Proposers' Day registration, or separately via this link. Teaming profiles will describe the technical competencies, team capabilities, team composition, research areas of interest, unique facilities and other capabilities, as they relate to the RAPID Program, and desired technical/other competencies sought from other potential team partners. The profile will include, at a minimum:

- **Contact Information**: Name, organization, email, telephone number, mailing address, and website.
- **Organization Technical Competencies**: A brief description of the proposer's technical skills.
- **Competencies Sought:** Desired skills and/or capabilities from other potential team members, if applicable.

Specific content, communications, networking, and team formation are the sole responsibility of participants. ARPA-H does not endorse any participating organization or exercise any responsibility for improper dissemination of the team profiles.

Registration Information

Participants must register in advance through the registration website. There is no registration fee for the RAPID Proposers' Day. To allow sufficient time to organize lightning talks and the poster session in a manner that will be most beneficial to all participants, registration will close as specified in Section I.

Individuals who are unable to register because the deadline has passed, or capacity has been reached will be added to a waitlist. After registration closes, any space that opens up may be filled on a first-come, first-served basis from the waitlist. An online registration form and various other meeting details can be found at the registration website.

Adherence to attendance guidelines will be managed by RAPID Program staff. Upon entry to the meeting venue, all attendees will be required to present valid, government-issued photo identification.

All inquiries regarding the event should reference "RAPID Proposers' Day (ARPA-H-SN-25-124)" in the subject line of the email. Prior to submitting an e-mail inquiry, please check out the Questions and Answers already posted on the RAPID Program page as FAQs to see if your question is answered there.

V. DISCLAIMER

This SN is issued solely for information and potential new program planning purposes; the SN does not constitute a formal solicitation for solutions. Participation is voluntary and is not required to respond to subsequent ISOs (if any) or research solicitations (if any) on this topic. ARPA-H will not provide reimbursement for costs incurred in responding to this SN. Further, this announcement is not a request for solutions; any so sent will not be reviewed. Respondents are advised ARPA-H is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted under this SN.