**Request for Solutions**

# Evidence-Based Validation & Innovation for Rapid Therapeutics in Behavioral Health (EVIDENT) - Exploratory

**Solicitation Number:** ARPA-H-CXHUB-26-109

**Request for Solutions Issue Date:** 21 NOV 2025

**Solution Summary Due Date:** 22 DEC 2025

1:00pm Eastern Time Zone

ARPA-H

## Table of Contents

# 1.0 Introduction

## 1.1 The Advanced Research Projects Agency for Health (ARPA-H)

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 accelerate better health outcomes for everyone, reinforced by its core organizational values that emphasize innovation, agility, and high-impact results. ARPA-H is committed to solving the most challenging health problems by developing research and development (R&D) programs that accelerate breakthroughs that improve health outcomes, turning what seems impossible into tangible realities for better health. ARPA-H is pioneering entirely new approaches to address the toughest challenges across the health ecosystem, advancing high-risk, high-impact biomedical and health R&D that cannot be easily achieved through traditional research or commercial activities.

To execute its mission effectively, ARPA-H embraces industry best practices, including due diligence reviews of existing R&D activities, rigorous program design, competitive project selection, thorough performer evaluations, and active program management to ensure optimized and impactful resource use. ARPA-H employs an active portfolio development approach, identifying programs based on clearly defined problems in the health ecosystem, led by the expertise of ARPA-H Program Managers (PMs). This sets ARPA-H apart from other federal health R&D organizations, as ARPA-H does not follow a predetermined or passive portfolio approach. This distinction is crucial, allowing ARPA-H to fund programs with the greatest potential to transform the health ecosystem, rather than aligning funds with projects that offer only incremental improvements.

Finally, ARPA-H's streamlined funding process enables the agency to act swiftly and catalyze cutting-edge biomedical and health R&D. This empowers ARPA-H to rapidly address longstanding problems in the health ecosystem with leading-edge solutions while remaining agile in responding to emergent issues, avoiding delays common in more protracted funding award processes.

## 1.2 Customer Experience Hub Consortium

The ARPA-H Customer Experience (CX) Hub Consortium forms part of ARPANET-H, a nationwide health innovation network dedicated to the needs of people: listening to, learning from, and building trust with communities to enable access to critical health innovations for all Americans. This network will take a human-centered approach to design products and services that people enthusiastically adopt. In doing so, the ARPA-H Customer Experience Hub will drive user testing, adoption, and end-user access for ARPA-H projects by incorporating end-user considerations at all stages of research and development, reaching representative patient populations, and capturing insights as public goods for future use.

Members of the network will draw on user-centered design and research best practices and methodologies, providing access, capabilities, and support to effectively integrate user input. The network will also explore rapid prototyping capabilities to allow for quick turnaround of physical or digital materials that can aid in user testing scenarios and refinement based on feedback from customers and stakeholders.

Advanced Technology International (ATI) was awarded an Other Transaction (OT) agreement by ARPA-H to serve as the Consortium Management Firm (CMF) for the CX Hub Consortium.

## 1.3 Purpose:

1.3.1 Program Vision and High-level Objectives:

- Mental and behavioral health disorders, including depression, anxiety, and addiction, affect half of all Americans over their lifetime and drive nearly $200 billion in annual treatment costs, with

depression projected to become the leading cause of disease burden by 2030. Behavioral health problems fuel chronic diseases including cardiovascular disease, diabetes, obesity, and Alzheimer's and multiply healthcare costs. Despite this substantial impact, current diagnostics rely on subjective endpoints and are not matched to individual needs, resulting in a "trial-and-error" approach that limits innovation and contributes to the growing disease burden.

- Emerging rapid-acting treatments for mental and behavioral health—including neuroplastogens (compounds that quickly promote neuroplasticity, such as ketamine and psilocybin), neuromodulation, digital therapeutics, and other novel approaches—are demonstrating the potential to deliver clinically meaningful improvements within days, hours, or even minutes. These interventions encompass a diverse range of modalities, yet progress remains constrained by continued reliance on subjective endpoints.
- The Evidence-Based Validation & Innovation for Rapid Therapeutics in Behavioral Health (EVIDENT), aims to catalyze a new era in behavioral health by generating and validating objective FDA-ready clinical endpoints for emerging therapies, enabling rapid, personalized, and durable improvements in mental and behavioral health. By the end of the current effort, ARPA-H will produce gold-standard objective measures and an ARPA-H designated Data Repository to support future research and regulatory acceptance of emerging rapid-acting therapies. The current effort will enable better health outcomes through robust objective and predictive measures of intervention effects, improving the ability to identify when a specific therapy will be most effective and for whom, as well as monitoring rapid treatment effects when they are occurring. This will reduce the burden of mental illness, lower healthcare costs, and improve quality of life for millions of Americans. Commercially, the approach will drive new standards for drug development and clinical care, with broad public health impact. In addition, the current effort paves the way for gold-standard measurement and identification of mechanisms for other types of behavioral health interventions.

1.3.2 Summary of What's Being Solicited:

ARPA-H is seeking solutions for innovative technologies that address Section 2.3. Technical Areas and Scope of Work. These technical areas (TAs) involve examination of multimodal data collected in the context of emerging rapid-acting intervention research for behavioral health. Each Solution Summary will be evaluated on its own merit. ARPA-H is under no obligation to respond to every submission, proceed with any Solution Summary or Solution Pitch, or select any specific number of Solution Summaries or Solution Pitches in each technical area. ARPA-H may also elect to fund one, several, or none of the proposed approaches to a given technical area.

- The solicitation for TAs 1–3 will be conducted as a single solicitation with a maximum period of performance of 24 months. Programs will have active ARPA-H program management, and payment will be associated with completion of defined milestones, including data collection, quality, delivery and early scientific findings. Additionally, there will be an annual performance review. This structure ensures accountability while allowing flexibility to adapt approaches as data and insights evolve.
- Awards are designed to augment existing data collection and measurement protocols, not to provide primary funding for studies recruitment activities.
- All awarded teams shall provide deidentified data and biospecimens (as applicable) to the ARPA-H designated Data Repository, to include all data and biological samples collected, generated, and developed under this Agreement. Preference will be given to teams who can provide complete, deidentified study datasets (e.g., also include all data collected during the conduct of studies funded by other entities).

- The ARPA-H Data Repository partner will be determined by a mechanism outside of this solicitation; ARPA-H is not soliciting proposals for the Data Repository partner presently.
- Collaboration among performers will be encouraged but not mandatory, particularly for cross-validation of results, harmonization of methodologies, and coordination for standardized data submission.

Across TAs, EVIDENT seeks to generate transformative, objective, and predictive measures of behavioral health response to rapid-acting interventions, replacing subjective clinical endpoints with quantifiable, FDA-ready biomarkers and models.

# 2.0 Technical Background

## 2.1 Background and Rationale

Given the significant burden of mental and behavioral health problems, and their link to multiple chronic health conditions, there is an urgent need for rapid, personalized, and durable interventions. Emerging, rapid-acting interventions, such as neuroplastogens, neuromodulation, and digital therapeutics, are promising solutions, yet mechanisms of action, predictors of efficacy, and safety profiles are poorly understood, and the lack of robust, objective data collection impedes regulatory progress and clinical adoption. As a result, despite their promise to disrupt behavioral health care, rapid-acting interventions remain constrained by the same challenges that have hindered progress in the field for decades.

To accelerate progress of emerging interventions for behavioral health, EVIDENT will invest in exploratory studies to operationalize and validate objective measures of rapid clinical effects. These efforts will focus on gold-standard measurement, mechanisms of rapid, in-session change, and personalized risk and durability profiles to facilitate treatment matching. Emphasis is on collection of real-time, high-resolution data to uncover digital and biological biomarkers of rapid neuroplastic and clinical change. Recent advances in wearable technology, digital health, and biological sampling now enable scalable, unobtrusive measurement of rapid treatment effects. ARPA-H provides the infrastructure and urgency to coordinate these efforts, making it possible to achieve what was not feasible even five years ago.

Deidentified data collected by these exploratory studies—and additional data and biological specimens collected as part of planned data repository efforts—will be curated and stored to enable and accelerate future discoveries. EVIDENT will enable better health outcomes through robust, objective, and predictive measures of intervention effects, improving the ability to identify when a specific therapy will be most effective and for whom, as well as monitoring rapid treatment effects when they are occurring.

## 2.2 Technical Objectives and Key Challenges

EVIDENT is organized around three exploratory TAs. These TAs involve examination of multimodal data collected in the context of emerging rapid-acting intervention research. Data pertaining to any emerging rapid-acting intervention with prior evidence of safety in humans and of producing rapid clinical effects (e.g., within 1-2 weeks) for mental and behavioral health symptoms or disorders is in-scope. For example:

- Neuroplastogens may include ketamine, ibogaine, scopolamine, psilocybin, lysergic acid diethylamide (LSD), dimethyltryptamine (DMT), etc.
- Neuromodulation may include transcranial magnetic stimulation (TMS), transcranial electrical stimulation (tES), focused ultrasound, transcutaneous vagus nerve stimulation (tVNS), etc.
- Digital therapeutics may include virtual reality (VR), smartphone apps, etc.

Both behavioral health symptoms (e.g., preclinical, subclinical, mild-to-moderate) as well as disorders are in-scope. Behavioral health conditions of interest include anxiety, depression, substance use disorder, and posttraumatic stress disorder (PTSD), but others may be considered. Strong TA 1-3 proposals will incorporate thoughtful inclusion of Veterans as well as broader groups in study protocols.

Out-of-scope studies include data collected in the context of other interventions that have not demonstrated the capability for rapid effects and other interventions that do not have prior evidence of safety in humans or prior evidence of clinical effect for improving behavioral health. Data from pre-clinical animal studies is out of scope.

Proposers applying to TAs 1-3 may: (1) analyze existing data, or (2) collect and analyze new data collection supplementary to existing study protocols. Awards are designed to augment existing data collection and measurement protocols, not to provide primary funding for studies recruitment activities.

Strong TA 1-3 proposals will augment existing clinical trials with new, multimodal data collection, but additional strong proposals will be considered outside the context of clinical trials. Teams may propose to collect additional supplemental data from a subset of enrolled participants, from entire samples, or during follow-up assessments. Data collection from intervention, control, and healthy participants is all within scope. Preference will be given to teams who have one or more FDA clinical endpoints included in their protocols.

Proposers can apply to one or more TAs. If applying to more than one TA, a separate Solution Summary submission is required for each. All awarded teams will provide deidentified data to the ARPA-H designated Data Repository. Deidentified datasets will include all data acquired, collected, and used for analyses under the current awards, with preference given to teams who can provide complete deidentified study datasets (e.g., also include all data collected during the conduct of a study funded by some other entity).

### 2.3 Technical Areas and Scope of Work

#### 2.3.1 Technical Area 1: Objective Measurement of Clinical Change

Current behavioral health endpoints are predominantly subjective and lack the temporal granularity needed to capture the onset and evolution of rapid-acting effects. Performers addressing TA1 will identify biological, digital, and physiological biomarkers of rapid clinical effects by leveraging multimodal data—including neuroimaging, digital phenotyping, and other biopsychosocial data collection—to monitor neuroplastic and clinical changes on a timescale of hours to days (Table 1). Desired solutions will combine neuroimaging, wearable, and digital phenotyping data to establish measurable indicators of treatment response and recovery.

Analogous to continuous glucose monitoring (CGM) in diabetes care, the long-term goal is the ability to measure continuously, with minimally invasive and scalable technology, an indicator of behavioral health, be it a single biomarker or composite index of multiple biomarkers. Therefore, the goal for TA1 is to identify likely indicators for continuous behavioral health monitoring. Performers will discover new candidates for future clinical endpoints that reflect both immediate and sustained therapeutic impact. This capability will allow individuals and providers to monitor and respond to fluctuations in illness and wellbeing, both in the present moment and on a predicted future trajectory.

**Table 1. Data of Interest***

| Type of Data | Examples |
|---|---|
| Brain imaging | Neuroplasticity, coherence, network connectivity, neuroinflammation |
| Digital physiological | Heart rate, heart rate variability, blood pressure, respiratory rate, pulse oximetry, skin conductance, body temperature, movement/activity (e.g., accelerometers, video), facial expression, voice analysis |

| | |
|---|---|
| Hormones | Cortisol, adrenocorticotropic hormone (ACTH), oxytocin, serotonin (5-HT), dopamine, melatonin, adrenaline, testosterone, estrogen, thyroid hormones |
| Inflammation | C-reactive protein (CRP), interleukins, tumor necrosis factor-alpha (TNF- α) |
| Neurotropic factors | Brain-derived neurotrophic factor (BDNF), nerve growth factor (NGF) |
| Metabolic markers | Glucose, insulin, lipids (cholesterol, triglycerides, lipoproteins) |
| Psychological data | Behavioral health symptom severity, positive/negative affect |
| Social data | Social connectedness, changes in homestay |
| Oxidative/cellular stress markers | Reactive oxygen species (ROS), antioxidant enzyme levels (e.g., superoxide dismutase, glutathione peroxidase), lipid peroxidation products |
| Other | Genotyping for relevant polymorphisms (e.g., 5-HT2A receptor), DNA methylation patterns, microbiome profiling, proteomic and metabolomics, neurotransmitter metabolites |

**This is a non-exhaustive list. Proposers may propose other biomarkers for collection and analysis along with justification of plausible mechanism of action on behavioral health.*

2.3.2 Technical Area 2: Mechanisms of Rapid, In-Session Change

The context and dynamics of therapeutic sessions are likely critical determinants of outcome but have not been systematically examined in existing research. Innovative, unobtrusive approaches to monitoring dyadic interactions between patient and facilitator are needed to discover interpersonal and therapy dynamics that increase effectiveness. TA2 performers will capture in-session data from patients (e.g., Table 1), facilitators (e.g., therapists, guides, monitors), and/or the environment (e.g., setting, lighting, temperature) to enable identification of real-time predictors of clinical change. Desired solutions will use unobtrusive sensors, EEG, and/or behavioral analytics to map predictors of clinical effectiveness during treatment sessions. EEG in-session is encouraged, but proposals must describe an unobtrusive set-up (e.g., comfortable and wireless) and ability to collect data from locations of primary interest for examining neural indicators of rapid effects (e.g., auditory and visual cortex in addition to frontal).

TA2 performers will acquire and analyze existing data or augment existing protocols to collect and analyze data that answer one or more of the following questions:

1. What is happening for the person in the moment that predicts effectiveness?
2. What is happening between the person and the facilitator that predicts effectiveness?
3. What are the environmental conditions that facilitate effectiveness?

2.3.3 Technical Area 3: Personal Risk and Durability Profiles

Personalized behavioral health care requires prediction of both risk and long-term benefit from rapid-acting interventions. TA3 performers will integrate clinical, genetic, and biomarker to develop predictive models that determine: (1) who is at-risk for an adverse event, and (2) who is most likely to respond to treatment immediately and with a durable effect at 3-, 6-, and/or 12-months following treatment. TA3 performers will acquire and analyze existing data or augment existing protocols to collect and analyze data that incorporate multimodal data streams (e.g., Table 1). TA3 performers may use extant or new data collection to generate actionable insights for treatment-matching, risk mitigation, and monitoring. The goal is to enable early identification of who will respond to a rapid-acting therapy, who has other underlying health factors that preclude specific interventions, and which intervention is indicated to achieve durable effects for a given individual.

### 2.4 Outcomes/Innovation Targets

Overall objectives, metrics, success criteria, and deliverables for EVIDENT are as follows:

- Identification of at least two objective clinical endpoints for rapid-acting interventions for behavioral health conditions (e.g., depression, PTSD)
- Regulatory engagement resulting in FDA feedback or acceptance of at least one new clinical endpoint
- Demonstration of predictive models for rapid clinical response and durability at 3-months minimum, 6- and/or 12-months ideally
- Delivery of deidentified datasets and biological samples to ARPA-H for ongoing analysis and innovation

Note these are overall program goals, not goals for specific technical areas or performers. Proposers should include their unique objectives, metrics, success criteria, and deliverables in their Solution Summaries.

### 2.5 Expected Deliverables/Milestones

Awards will have a maximum period of performance of 24 months, structured intentionally to supplement existing efforts through modifications or amendments to existing IRB protocols. All exploratory TA 1-3 performers shall submit a complete IRB protocol, either approved or under review at time of solution summary submission, to indicate that an existing study has already been planned, funded, and is able to secure all necessary regulatory approvals for completing EVIDENT required milestones. Proposed IRB amendments for supplemental data collection and/or analysis shall be submitted by awarded performers by kick-off.

Programs will have active ARPA-H program management, and payment will be associated with completion of defined milestones, including data collection, quality, delivery and early scientific findings. There will be an annual performance review. All performers will deliver and demonstrate preliminary results by month 12.

Example Milestones (Proposers may specify their own Milestones in their Solution Summary):

- Kick-off: Submission of amendments to approved IRB protocols
- Month 3: IRB approval for supplementary data collection
- Month 6: 20% of planned data collected and delivered to Data Repository; Preliminary report including basic demographics and descriptive statistics submitted
- Month 9: 40% of planned data collected and delivered to Data Repository; updated report submitted
- Month 12: 60% of planned data collected and delivered to Data Repository; updated report submitted; annual performance evaluation
- Month 15: 80% of planned data collected and delivered to Data Repository; updated report submitted
- Month 18: 100% of planned data collected and delivered to Data Repository; updated report submitted
- Month 21: Preliminary analyses complete; updated report submitted
- Month 24: All deidentified data and biological samples delivered to Data Repository; final analyses complete; final report submitted

### 2.6 Data Management/Tech Transfer/Access Requirements

All awarded teams shall provide deidentified data and biospecimens (as applicable) to the ARPA-H designated Data Repository, to include all data and biological samples collected, generated, and developed under this Agreement. Ideally, teams will also be able to provide complete, deidentified clinical trial datasets (e.g., also include all data collected during the conduct of the clinical trial funded by

other entities). Submission of deidentified data must include data on one or more FDA-approved clinical endpoints.

## 3.0 Program Structure and Coordination

EVIDENT awards will have a maximum period of performance of 24 months. Programs will have active ARPA-H program management, and payment will be associated with completion of defined milestones, including data collection, quality, delivery and early scientific findings. There will be an annual performance review. Collaboration among performers is strongly encouraged to ensure interoperability of data, methodological alignment, and collective learning across the three technical areas. All TAs will contribute deidentified data, biospecimens, and supporting documentation (e.g., data dictionaries, code) to the ARPA-H designated Data Repository.

### 3.1 Performer Expectations

- Performers will be required to submit deidentified data and biospecimens to the Data Repository following ARPA-H data governance standards (forthcoming).
- Collaboration among performers will be encouraged, but not mandatory, to coordinate data standardization, troubleshoot integration challenges, and align regulatory compliance.
- Performers will ensure all milestones documentation is submitted on time.
- Performers will participate in required coordination meetings and events, including a program kickoff, a 12-month ARPA-H review, and a final close-out meeting. In addition, quarterly hybrid technical exchanges will allow teams to share lessons learned, integration progress, and regulatory updates. There will also be an optional hybrid Proposers' Day.
- Performers will ensure that all regulatory documentation, IRB protocols, and data-sharing agreements are in place and maintained throughout the program.

### 3.2 Role of ARPA-H

- The ARPA-H Program Manager (PM) will serve as the central oversight authority, ensuring all TAs remain aligned with program objectives, timelines, and ethical standards. The PM will review all technical and financial reports, assess milestone completion, and provide actionable feedback to performers.
- ARPA-H will engage directly with performers through monthly progress check-ins, quarterly reviews, and targeted technical discussions to address challenges and ensure alignment.
- ARPA-H will also establish a continuous feedback loop with performers to quickly resolve technical and operational issues as they arise. As the funding agency, ARPA-H retains the authority to redirect priorities, down-select underperforming teams, reallocate resources, or reassign work if milestones are not met or if program objectives shift.

### 3.3 Role of Consortium Management Firm

- The Consortium Management Firm (CMF) will provide administrative and operational support for awards. The CMF will be responsible for onboarding performers, ensuring compliance with the RFS requirements from submission to award, and executing agreements.
- The CMF will serve as the primary communication bridge between ARPA-H and performers, facilitating regular updates and coordinating meetings. The CMF will also manage budget tracking, financial compliance, and consolidated milestone reporting, submitting unified technical and financial progress reports to ARPA-H in alignment with agency templates and schedules.

### 3.4 Program Funding/Budget

- Funding for TAs 1–3 will follow a fixed-price, milestone-based structure, with payments contingent upon successful completion of defined deliverables. There will be an annual performance evaluation.
- Each award is expected to be a fixed $4 million total over a maximum 24-month period.

### 3.5 Performance Reporting and Status Review

- Performers will provide monthly technical updates and quarterly comprehensive progress reports outlining data collection status, participant metrics, and analytical milestones. Reports will include descriptive statistics, preliminary analyses, and summaries of multimodal data acquisition.
- ARPA-H will conduct a formal performance review at 12 months, supported by the Data Validation performer (to be determined) in collaboration with the ARPA-H designated Data Repository to confirm data integrity, analysis validity, and milestone achievement.
- Teams will be required to maintain detailed documentation of methodologies, datasets, and analytic pipelines. Data submissions will occur on a rolling quarterly basis, with all deidentified data delivered to ARPA-H designated Data Repository by project completion.

## 4.0 Eligibility

All responsible sources capable of satisfying the Government's needs may submit to the RFS. The government will not make an award to a team that includes Federally Funded Research and Development Centers (FFRDCs) or other Government Entities—either at the prime or subawardee level (at any tier).

Non-US Entities: ARPA-H will prioritize awards to entities (organization and/or individuals) that will conduct funded work in the United States. However, 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. In accordance with these laws and regulations, 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. Ch 44 § 3059)]; a foreign entity of concern meeting any of the criteria in section 10638(3) of the CHIPS and Science Act of 2022; [an individual that is party to a malign foreign talent recruitment program, as defined in Section 10638(4) of the CHIPS and Science Act of 2022]; or entities suspended or debarred from business with the Government.

### 4.1 Award Eligibility

All entities who meet the above criteria may respond to this RFS. Eligible entities who submit a compliant Solution Summary and are invited to submit a Solution Pitch will be required to first submit an application to become a Consortium Member (i.e., a Spoke) at https://www.customerexperiencehub.org/how-to-join/.

Prior to receiving a Project Award, all performers must execute a CX Hub Base Agreement, which is governed by the OT Agreement between ARPA-H and ATI. A copy of the CX Hub Base Agreement can be found on the CX Hub Member's Only website: https://private.customerexperiencehub.org.

System for Award Management (SAM): A SAM.gov Unique Entity Identifier (UEI) is required for award.

NOTE: New SAM registrations and renewals may take more than 14 business days to process. SAM is independent of ARPA-H and thus ARPA-H representatives have no influence over processing timeframes.

# 5.0 Evaluation and Selection Methodology

## 5.1 Evaluation Process

5.1.1 Compliance Screening

The CX Hub CMF will conduct a preliminary screening of Solution Summaries to ensure compliance with the RFS requirements. As part of the preliminary screening process, Solution Summaries that do not meet the requirements of the RFS may be eliminated from the competition or additional information may be requested by the CX Hub CMF. The Government reserves the right to request additional information or eliminate Solution Summaries that do not meet the requirements of the RFS from further consideration.

5.1.2 Solution Summary

All proposers must submit a Solution Summary. Solution Summaries must clearly align to one RFS technical area (Section 2.3) and comply with all requirements detailed in this RFS. If applying to more than one TA, a Separate Solution summary submission is required for each. Solution Summaries may not exceed 6 single-sided pages and must conform to the requirements in Appendix A. ARPA-H will evaluate submitted Solution Summaries based on the evaluation criterion below. As a result of the Government's evaluation, some proposers will be invited to provide a Solution Pitch. Note that a proposer's Solution Summary may be evaluated to be of merit but not invited for a Solution Pitch. Those not invited to the Solution Pitch phase will be notified via email. No additional feedback will be provided.

5.1.3 Solution Pitches

Proposers invited to provide a Solution Pitch will be informed via email of their designated day and time. **All required submission documents will be due one week in advance of the scheduled pitch.** Note that cost proposal documentation is not required, given the $4 million fixed awards. Proposers will also be given templates for the following required submission documents:

- Statement of Work (SOW)
- Solution Pitch Deck
- Administrative and National Policy Requirements Document
    - Biographical Sketch
    - Current and Pending Support

During the Solution Pitches sessions, which may be virtual or in-person, the proposing team will present their capabilities to the ARPA-H team. Each proposer will have 15 minutes to present followed by a 30-minute Question and Answer (Q&A) session. All pitches may be recorded to allow for later review. Proposers will be expected to submit a slide deck (using the provided template), in either PPT or PDF form, and present an interactive, web-compatible demonstration of the capability/capabilities. The Solution Pitch approach will allow ARPA-H to evaluate the submissions quickly and efficiently.

ARPA-H will evaluate the solution pitches based on the stated evaluation criteria in Section 5.2.

## 5.2 Evaluation Criteria

ARPA-H will evaluate the Solution Summaries and Solution Pitches based on consideration of scientific and technical merit, feasibility, and innovation of the solution, given the $4 million fixed award. ARPA-H

will use the criteria to determine which submissions will be invited to move to the next phase of the evaluation process and ultimately be selected as most advantageous to the Government.

### 5.3 Collaboration & Alignment (C&A)

After evaluating the Solution Pitches, the ARPA-H team will select proposers to proceed to the C&A Phase. Proposers will be notified via email after their Solution Pitch if they are selected or not selected to move onto C&A. Notifications will not occur until after all pitches have concluded and been adequately evaluated. ARPA-H reserves the right to limit the number of proposers invited to C&A. As such, a proposer's Solution Summary and Solution Pitch may be evaluated to be of merit but not invited to C&A. Those not invited to C&A Phase will be notified via email. No additional feedback will be provided.

The selected proposers will work with ARPA-H to collaboratively refine the submitted Statement of Work (SOW).

*The Government will not pay proposers for costs associated with any elements of the proposal/evaluation process (e.g., Solution Summary, Solution Pitch, C&A, or travel), unless otherwise stipulated.*

### 5.4 Award Selection

Once the Government and proposer have successfully completed the C&A Phase, the Agreements Officer (AO) will issue a Technical Direction Letter (TDL) to the Customer Experience (CX) Hub CMF. The TDL triggers the CMF to issue a Project Award to the selected proposer. Each TDL and resulting Project Award will incorporate the collaborative SOW, associated price, and other pertinent project details. All TDLs and Project Awards will be governed by the CX Hub Base Agreement. Specific terms and conditions for this solicitation will be made available prior to Proposers' Day.

### 5.5 Government Stipulations

The government reserves the right to select for negotiation all, some, one, or none of the proposals received in response to this RFS. If warranted, portions of resulting awards may be segregated into pre-priced options. In the event the government desires to award only portions of a proposal, C&A will commence upon selection notification. The government reserves the right to fund proposals in phases with options for continued work, as applicable.

The government reserves the right to request any additional necessary documentation to support the C&A and award process. The government reserves the right to remove a proposal from award consideration should the parties fail to reach agreement on award terms, conditions, price, and/or if the Proposer fails to provide requested additional information in a timely manner.

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).

## 6.0 Data/IP (Delivery and Rights)

The following will apply to all project awards made as a result of this solicitation. The RFS Data/IP terms will take precedence over the Data Rights terms outlined in Article 8 of the CX Hub Base Agreement.

The Project Awardee shall deliver all research data generated, collected, developed, or used under this Agreement to the ARPA-H designated Data Repository. The Project Awardee shall follow the instructions provided in the Standard Operating Procedures (SOPs), which will provide guidance on submitting data

to the ARPA-H designated Data Repository. These SOPs will be provided through an amendment to this solicitation.

The Government will retain a worldwide, fully paid-up, nonexclusive, royalty-free license to the research data. This license includes the right to sublicense the data. The Government may use, modify, reproduce, release, perform, display, or disclose the research data: (i) within the Government, (ii) with authorized personnel, or (iii) with any federal contractor, grantee, or party to a cooperative agreement or other transaction. These rights may be exercised for any health, health care, or medical-related research purpose, as well as for purposes related to the administration of this Agreement.

## 7.0 Human Subjects Research

All proposers submitting a funding proposal that will involve engagement in Human Subjects Research (HSR) (as defined in 45 CFR § 46) must provide documentation of one or more current Assurance of Compliance with federal regulations for human subjects protection, including at least a Department of Health and Human Services (HHS), Office of Human Research Protection Federal Wide Assurance. All human subjects research must be reviewed and approved by an IRB, as applicable under 45 CFR § 46 and/or 21 CFR § 56. The entity's human subjects research protocol must include a detailed description of the research plan, study population, risks and benefits of study participation, recruitment and consent process, data collection, and data analysis. Recipients of ARPA-H funding must comply with all applicable laws, regulations, and policies for the ARPA-H funded work. This includes, but is not limited to, laws, regulations, and policies regarding the conduct of human subjects research, such as the U.S. federal regulations protecting human subjects in research (e.g., 45 CFR § 46, 21 CFR § 50, § 56, § 312, § 812) and any other equivalent requirements of the applicable jurisdiction.

The informed consent document utilized in human subjects research funded by ARPA-H must comply with all applicable laws, regulations, and policies, including but not limited to U.S. federal regulations protecting human subjects in research (45 CFR § 46, and, as applicable, 21 CFR § 50). The protocol package submitted to the IRB must contain evidence of completion of appropriate human subjects research training by all investigators and key personnel involved in the design or conduct of the ARPA-H funded human subjects research. Funding cannot be used toward human subjects research until ALL approvals are granted.

## 8.0 Key Dates

| **Item** | **Date*** |
|---|---|
| Request for Solutions (RFS) posted | 21 NOV 2025 |
| Proposers' Day | 10 DEC 2025<br>8:00-4:30pm ET (est.) |
| Submission Portal Opens | 11 DEC 2025 |
| Questions Deadline | 12 DEC 2025 |
| Solution Summary Deadline | 22 DEC 2025<br>1:00pm ET |

## 9.0 Points of Contact

For inquiries on this solicitation, please direct your correspondence to the following contacts:

Contractual questions related to this RFS should be directed to the CX Hub Contracts Manager, Taylor Hummell, arpa-h-cx-hub-contracts@ati.org

Technical and membership questions should be directed to the CX Hub Program Manager, Sarah Bailey, arpa-h-cx-hub@ati.org

## 10.0 Appendices

A. Solution Summary Template

B. BIDS Instructions/Submission Guide

## Appendix A–Solution Summary Template

1. **General Information**

   a. All Solution Summaries must be submitted in English using 11-point Arial font. Smaller non-serif fonts may be used for figures, tables, and charts. Margins may be no less than one inch in width.

   b. Solution Summaries are limited to six pages, exclusive of a cover page and References. No table of contents shall be provided. The Government may not review pages beyond six (6) total (exclusive of cover page and references); and any Solution Summary submitted that exceeds 6 pages will only be reviewed at ARPA-H's discretion.

   c. Solution Summaries should be submitted in a PDF format to ATI's BIDS Submission System (See RFS Appendix B for instructions). Attachments and embedded links shall not be included.

   d. Solution Summaries must address only one specific Technical Area (TA); if applying to more than one TA, separate Solution Summaries are required.

2. **Cover Page**

   The cover page should follow the format below. The cover page does not count towards the page limit.

| | | |
|---|---|---|
| 1 | Solicitation # | ARPA-H-CXHUB-26-109 |
| 2 | Solution Summary Title | |
| 3 | Technical Approach (TA) Selection | |
| 4 | Submitter Organization | |
| 5 | Type of Organization and website URL if applicable | Choose all that apply: Large Business, Small Disadvantaged Business, Other Small Business, HBCU, MI, Other Educational, or Other Nonprofit |
| 6 | Technical Point of Contact (POC) | Name:<br>Mailing Address:<br>Telephone: Email: |
| 7 | Administrative POC | Name:<br>Mailing Address: Telephone: Email: |
| 8 | Total Estimated Budget (Choose 1 TA) | $4M (TA 1)<br>$4M (TA 2)<br>$4M (TA 3) |
| 9 | Place(s) of Performance | |

| | | |
|---|---|---|
| 10 | Other Team Members (sub-performers, including consultants) if any | Technical POC Name:<br>Organization:<br>Organization Type: |

3. **Proposed Work**

   a. Clearly identify which of the stated problems (TA1, 2, or 3) is being addressed, the outcome(s) sought with the proposed concept, and how this represents transformative capability.

   b. Describe the analytic goals and approach.

   c. Describe the sample that will be studied. Include objective milestones at each quarter during the proposed period of performance (e.g., number of participants recruited, data collected).

   d. Describe the final deliverable(s) for the project, key quarterly milestones, and the overall technical approach used to achieve project objectives. If this is commingled with existing work, please ensure deliverables and milestones are clearly delineated between currently funded projects and work associated with the ARPA-H effort.

   e. If applicable, provide an overview of any of the proposing organization's relevant, currently funded research and data already planned for collection in an existing clinical trial. Specify the value and methods in which ARPA-H funding is allowing expansion of existing data, in number, variety, or both.

4. **Team Organization and Capabilities**

   Indicate the roles and responsibilities of the organizations and key personnel that comprise the Performer Team, including level of effort for all key personnel. Provide the name, position, and institution of each key team member; and describe in 1-2 sentences the skills and experience they bring to the team.

5. **Risk**

   Identify any risks that may prevent you from reaching your objectives as well as any risks the TA itself may present (e.g., scientific/technical, budget, data, etc.). Please also describe plans to mitigate these risks at a high level.

6. **Data Strategy Compliance**

   Assert your agreement with the Government's data requirements; most specifically limited rights for the government to all data as well as the requirement to share data, deidentified to the greatest extent practicable, with the ARPA-H designated data repository. This includes data generated under this effort as well as any data included in deliverables.

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