PROPOSERS' DAY | 10 DEC 2025

EVIDENT

Evidence-Based Validation & Innovation for Rapid Therapeutics in Behavioral Health

Nate Mohatt, Ph.D.

Program Manager, Proactive Health Office (PHO)

Advanced Research Projects Agency for Health (ARPA-H)

Agenda

All times below are Eastern Time.

Time	Topic	Presenter
8:30am – 9:30am	Registration & Check-in	
9:30am – 9:45am	Welcome & Introduction	**Alicia Jackson,** Director, ARPA-H
9:45am – 10:30am	EVIDENT Program Description	**Glen Coppersmith,** Acting Director, Proactive Health Office **Nate Mohatt**, Program Manager, Proactive Health Office
10:30am – 10:45am	Break	
10:45am – 11:15am	Customer Experience Hub Introduction	**Mike Stebbins**, Sr. Vice President of Medical & Health Division **Sarah Bailey**, Program Manager
11:15am – 11:45am	BID OTA Overview	**Caitlin Burns,** Agreements Officer, ARPA-H
11:45am – 12:00pm	Morning Q&A and Morning Wrap-up	**Glen Coppersmith,** Acting Director, Proactive Health Office
12:00pm – 1:30pm	Lunch Break	
1:30pm – 4:15pm	One-on-Ones	
1:30pm – 4:15pm	Lightning Talks	
4:15pm – 4:30pm	Networking Break	
4:30pm – 5:00pm	Q&A and Closing Remarks	**Glen Coppersmith,** Acting Director, Proactive Health Office

ARPA-H

The ARPA-H Model

Alicia Jackson, Ph.D.

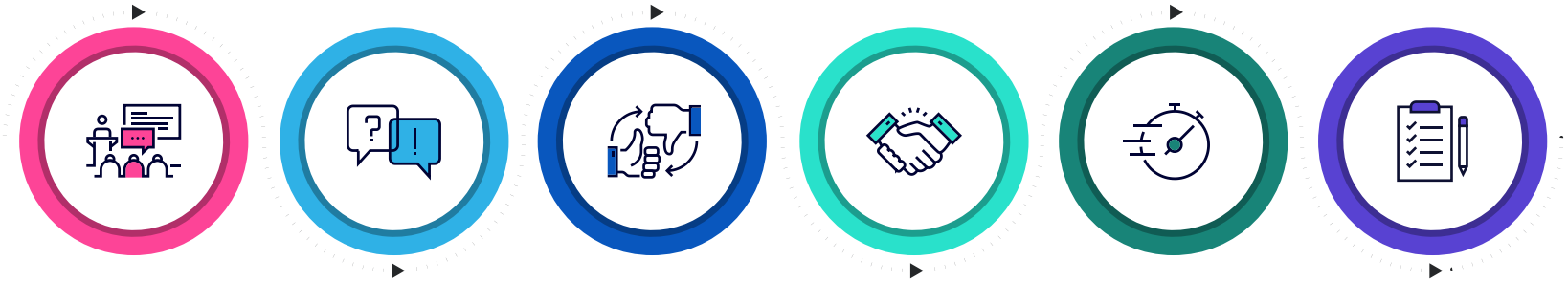
Director, ARPA-H

Who We Are

- Our agency is lean by design and disruptive by mission. We forge unconventional public-private alliances to develop transformative solutions, in areas from cancer to chronic disease to aging.
- We move at the speed of startups to tackle health care's toughest problems — not by expanding bureaucracy, but by unleashing the power of markets and innovation.
- We deploy flexible funding tools — primarily like Other Transactions — to accelerate results, increase accountability, cut costs, and attract the boldest minds from the private sector.

How it Works

Our Funding Award Process

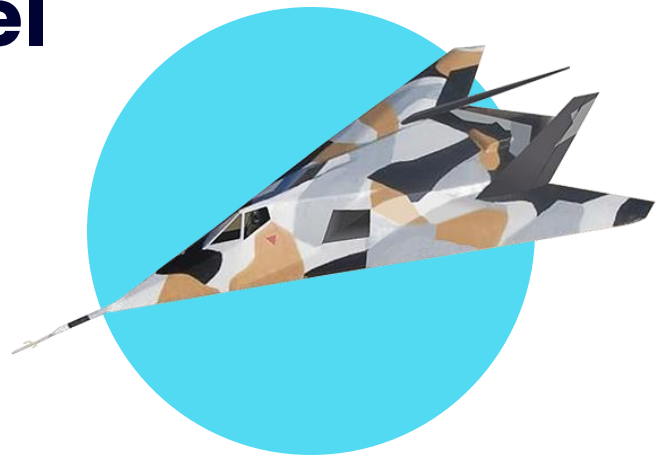


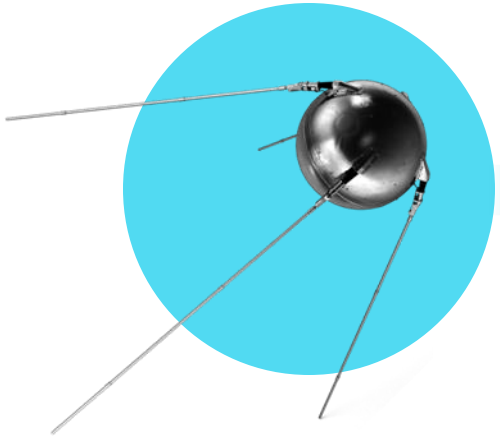
- Each program frames a challenge and awards projects to multidisciplinary teams, whose work is then measured and evaluated by our Program Managers, to ensure that only the best solutions advance.
- Programs start with commercialization as a priority and continue throughout the process to get solutions to deployment.
- Our rapid program development and deployment enables transformative advancements extending in a condensed timeline, up to 5 years, not decades.

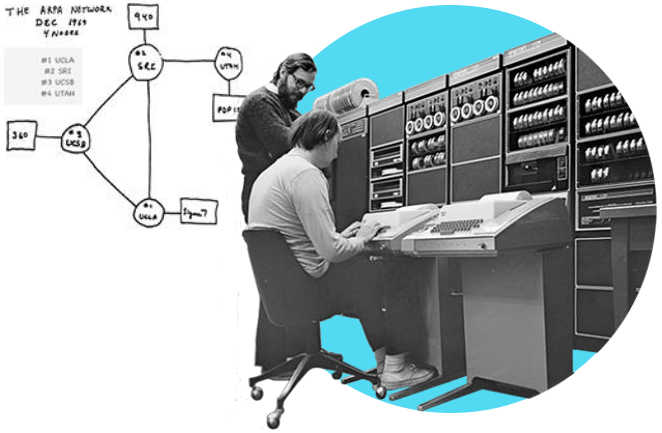
Administration Aligned Research Topic Areas:

ARPA-H

The Promise of the ARPA-H Model







ARPA-H Key Features and Authorities

ARPA-H has unique structures and legal authorities that allow it to **function like a business — quickly, nimbly, and decisively**.

- ARPA-H is a **funding agency**
- **Independent** component of HHS
- No internal research labs; **disease agnostic**
- Generally **fund outcome-based contracts,** not grants; accelerated award timelines
- Unique **FDA reimbursement authority**

FY 2022	FY 2023	FY 2024	FY 2025
$1B	$1.5B	$1.5B	Request: $1.5B

Lean and nimble management structure with autonomy in decision-making.

ARPA-H Director **reports directly to HHS Secretary.**

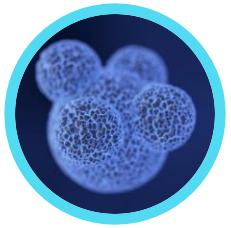
Term limits of 3-6 years bring urgency and idea flow.

Flexibility in hiring allows ARPA-H to recruit at levels competitive with industry.

Bottom-up decision-making. Program Managers have autonomy to make decisions quickly.

ARPA-H is a problems focused organization.

ARPA-H: The ARPA Model at Work for Health



HOW?

We are a unique funding agency *by design*

WHO?

Problem-focused Program Managers (PMs) drive innovation

WHAT?

We are seeking radical change

Attributes that Support the Mission

Radical Change

ARPA-H investments should seek to address seemingly impossible barriers in demonstrating "proof of concept" for solutions to major challenges — not incremental advances.

Autonomy

PMs practice "full contact" management to maintain vision and deliver results, with metrics/milestones for programs, empowered to stop underperforming projects.

Term limits

Terms limited to 3 years (renewable once for 6 total years) for PMs, Office Directors, and Deputy Directors, allowing inflow of new ideas.

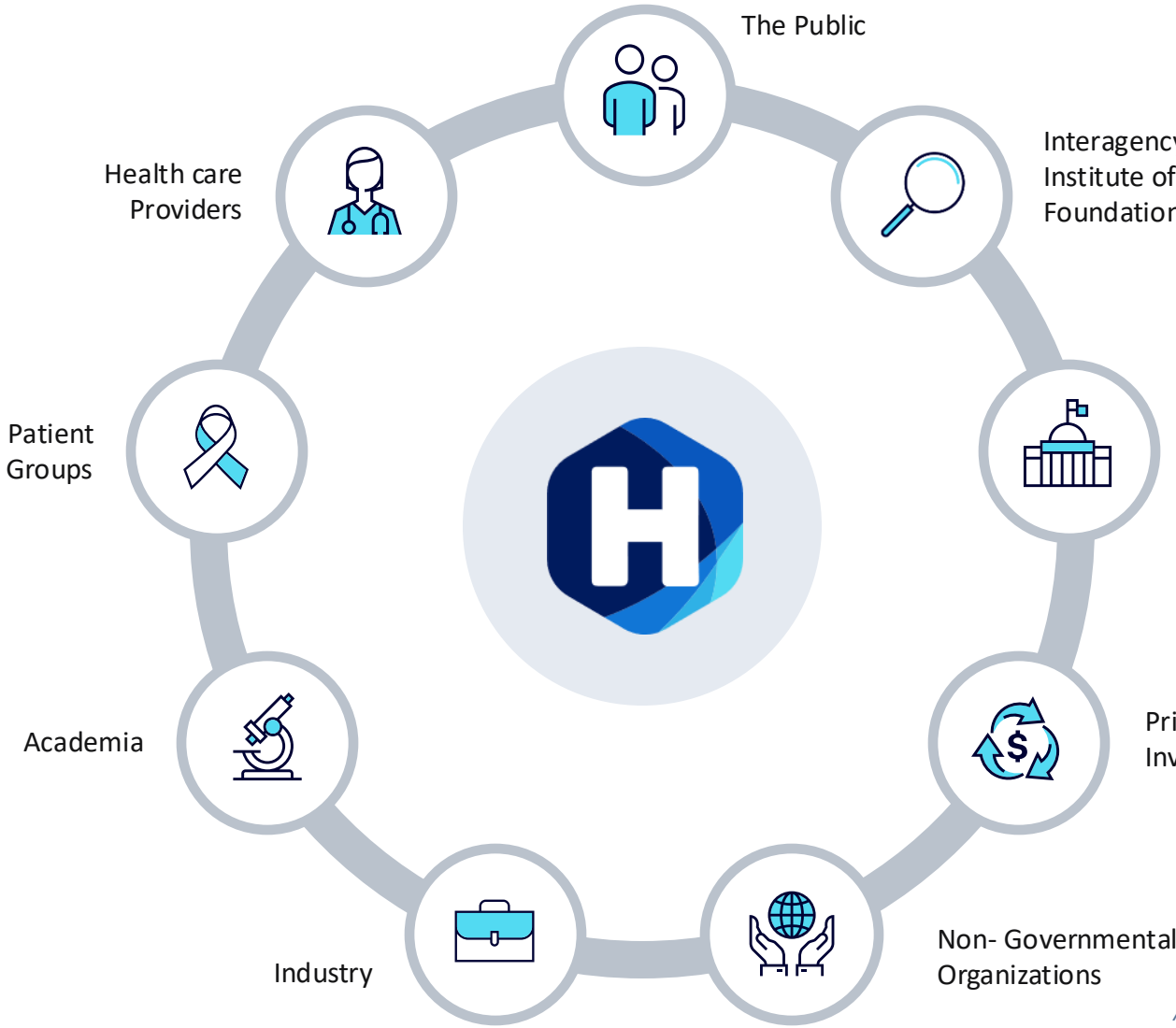
Success for ARPA-H is defined by real-world impact

ARPA-H Accelerates the Entire Health Ecosystem

STAKEHOLDERS

CUSTOMERS

PERFORMERS



(and many others …)

ARPA-H

ARPA-(H)eilmeier Questions

Towards a well-defined problem

1. What are you trying to do? What health problem are you trying to solve?
2. How does this get done at present? Who does it? What are the limitations of present approaches?
3. What is new about our approach? Why do we think we can be successful at this time?
4. Who cares? If we succeed, what difference will it make? What health outcomes are we accelerating?
5. What are the risks that may prevent you from reaching your objectives? Any risks the program itself may present?
6. How long will the program take?
7. How much will the program cost?
8. What are our mid-term and final exams to check for success?
9. How will cost, accessibility, and user experience be considered to reach everyone?
10. How might this program be misperceived or misused (and how can we build trust and prevent that from happening)?

ARPA-H Model: Program Lifecycle

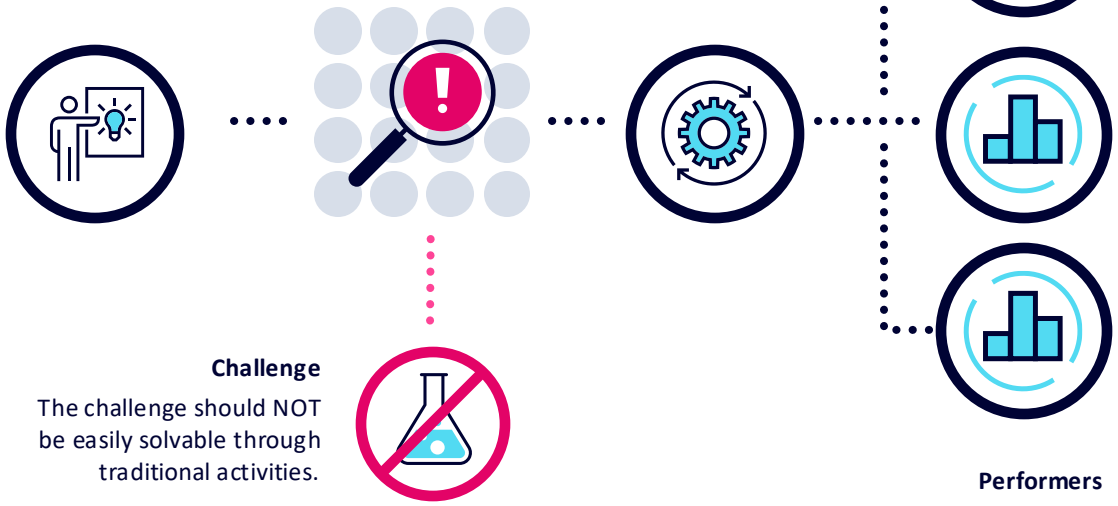
LAUNCH

Program Manager

Program Manager identifies a difficult health-related challenge that is ripe for solving.

Program Launch

A Program Manager seeks — and oversees — several groups of performers aiming to solve the same problem in unique ways.



Challenge

The challenge should NOT be easily solvable through traditional activities.

Performers

Performers compete to carry out their potential innovative solutions to the challenge.

Support

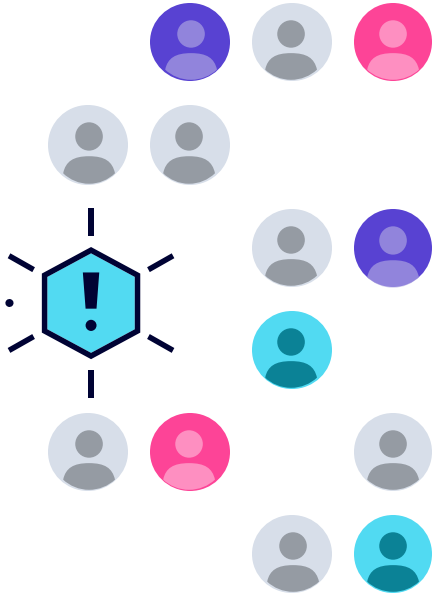
ARPA-H will provide contracts – not grants – for projects with well-defined endpoints. Additional support will be provided by Program Managers, partners, and ARPA-H offices to ensure the best chance of success throughout the process.

PERFORM

Performance

Contract performance will be regularly evaluated to allow ARPA-H to concentrate resources on the most effective approaches to reaching the desired goals.

TRANSITION



Graduation

Graduation occurs when the challenge is solved. The project then transfers to partners, who have been involved from the start and can scale the solution for large, diverse communities everywhere.

ARPA-H

Program Lifecycle

From ideas to solutions in the real world

DESIGN PROGRAMS

- ARPA-Hard and well-defined problems in health
- Heilmeier framework
- High risk/High consequence
- Stakeholder Insights

BUILD A PERFORMER TEAM

- Solicit solutions from the community
- Find the best non-traditional, industry, and academics to solve
- Build new coalitions

EXECUTE & MEASURE

- Active program management against metrics
- Stakeholder engagement throughout to ensure transition
- Pivot resources when needed

LEARN & GROW

- Capture and share insights
- Technical honesty
- Advance the state of the art; 10x+ improvement, no incremental change

COMMERCIALIZE & TRANSITION

- Assist company formation or licencing
- Provide mentorship, connections to customers, investors
- De-risk investments

ARPA-H

The Program and Program Manager (PM) Flywheel

The ARPA-H portfolio is:

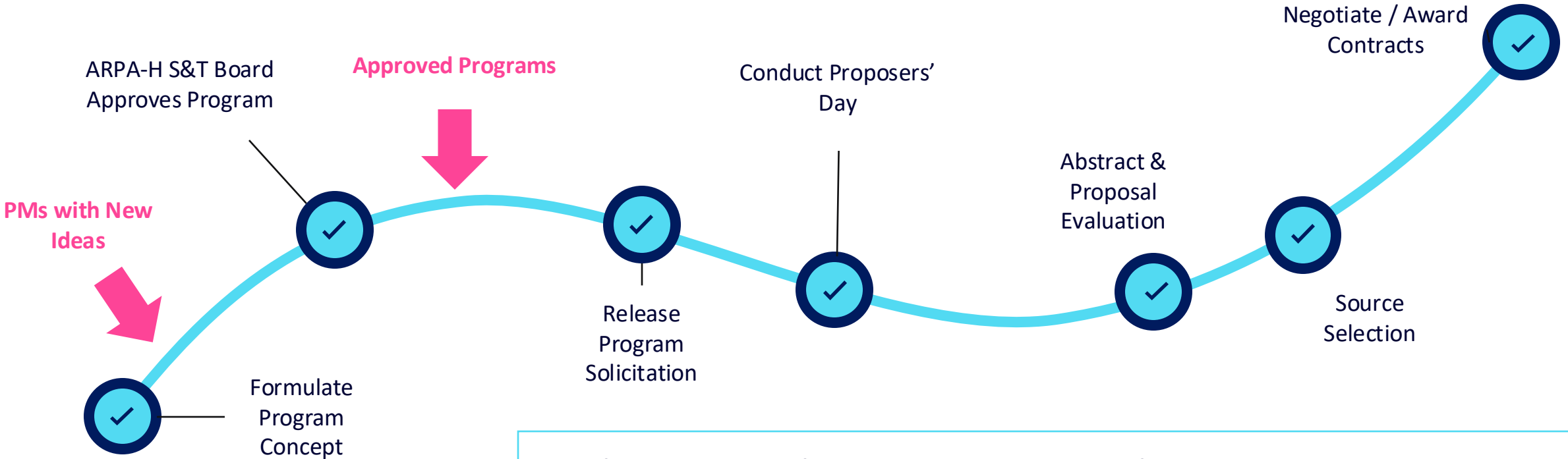
(1) a reflection of the PMs

(2) dynamic, and

(3) will — and should! — change frequently

Program Development Lifecycle

~9 months from concept to contract award



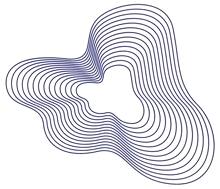
Key Elements to Launching ARPA-H Program Toward Success

- **Technical Discipline**
- **Due Diligence**
- **Financial Risk Management**

The time to formulate ARPA-H programs is 2-4 months (engage stakeholders and potential performers, develop metrics), followed by ~6 months from program approval to launch, evaluate proposals and negotiate contracts.

Initial Mission Focus Areas

Further ARPA-H investment in these areas will generate asymmetrical benefits to the health ecosystem.



Health Science Futures

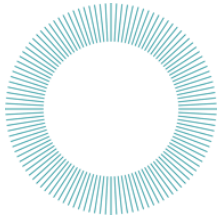
Expanding what's technically possible

Accelerate advances across research areas and remove limitations that stymie progress towards solutions. These innovative tools, technologies, and platforms apply to a broad range of diseases.

Scalable Solutions

Reaching everyone quickly

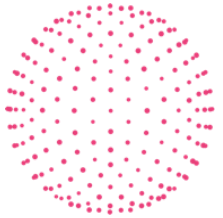
Address health challenges that include geography, distribution, manufacturing, supply chain, data and information, and economies of scale to create programs that result in impactful, timely solutions.



Proactive Health

Keeping people from getting sick

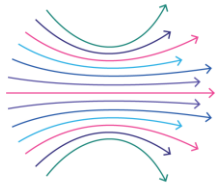
Prevent disease and extend the health span of all Americans through new capabilities to promote healthy physiology and detect or characterize disease risk. Promote treatments and behaviors to anticipate threats to health, whether those are viral, bacterial, chemical, physical, or neurological.



Resilient Systems

Building integrated health care systems

Develop capabilities, business models, and integrations to endure crises such as pandemics, social disruption, and economic instability. Resilient systems need to sustain themselves between crises – from the molecular to the societal – to better achieve outcomes that advance American health and wellbeing.

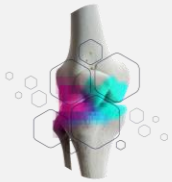


Office of Commercialization

Ensuring programs "survive in the wild"

Translate scientific and technical breakthroughs into real world products and services, ensuring they result
in better health outcomes for all Americans. OC serves the four technical mission offices to ensure innovations are enthusiastically adopted by
the private sector, providers, and patients.

ARPA-H Investment Portfolio Snapshot

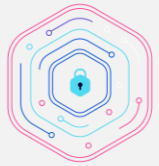


NITRO

What if we could make our joints heal themselves?

REACT

What if your body could make its own medicine?



DIGIHEALS

What if we could strengthen the nation's digital health infrastructure to protect against cyberattacks?

APECx

What if we could eliminate viruses as current and future health burdens?

PRINT

What if we could bioprint any organ on demand?

PROSPR

What if we had therapies to extend healthspan and prevent the onset of age-related diseases?

PARADIGM

What if we could deliver advanced hospital-level care to every rural county in America?

SPIKEs

What if programable bacteria could be directed to kill cancer inside the body?

DARTS

What if we could identify antibiotic-resistant bacteria in minutes?

MATRIX

What if we could immediately determine if FDA-approved drugs could treat rare and/or untreatable diseases?

ADAPT

What if we could adapt cancer treatments as tumors mutate and change?

RAPID

Rare Disease AI/ML for Precision Integrated Diagnostics

ARPA-H

ARPA-H Behavioral and Mental Health Topics

Glen Coppersmith, Ph.D.

Acting Director,
Proactive Health Office (PHO)

ARPA-H

ARPA-H Mental and Behavioral Health Topics

Objective: Addressing America's growing mental and behavioral health epidemic will require multiple radical changes. We must reimagine the system around answering the question **what works for this specific person, right now?**

1 in 2

Americans will have a behavioral health disorder during their lifetime[1]

Left unaddressed, these form a vicious cycle and **exacerbate other chronic diseases**[2-5]

Topic Focus Areas:

1: Widely adopted objective measurement. Measurements that capture what matters, are less time consuming, and are incentivized

2: Effective prevention and treatment for everyone. More durable evidence-based interventions, personalized to what each patient needs, and adjusted if they are not working

3: Reimagined system of care, with expanded capacity and improved training. Renewed focus on familial & community interventions, not just 1:1 treatments

Why ARPA-H:

- **Complexity:** Multiple things need to get fixed at once; fixing one-off problems is insufficient
- **Catalyze and focus industry:** Currently working on the margins as these foundations are "too big to move"

Potential specific efforts of interest:

- Biomarker identification
- Early, fast, effective prevention
- Interventionist training and treatment delivery
- Scaled-up prevention approaches

[1] Mental Health America, 2025; [2] Correll et al., 2017; [3] Graham et al., 2010; [4] Mannan et al., 2016; [5] Garcia-Garcia et al., 2023

Financial toll of behavioral illness is larger than heart disease or cancer

Costly: US spends nearly **$200 billion** on behavioral health treatments annually

Compounding: Behavioral illness exacerbates other chronic conditions, multiplying costs by **3-6x**

Total cost of behavioral health disorders	1 billion	$5 trillion	3-6x	$282 billion
	People are living with behavioral health condition, globally[1]	Global cost of mental health each year[2]	Greater healthcare cost vs. those without a behavioral health condition[3,4]	Economic cost per year (2024 USD)[5]

Estimated annual US healthcare spending (2019)[6]	$166 billion	$30 billion
	Mental disorders	Substance use

Estimated annual US spend, specific conditions (2019)	$41 billion	$38 billion
	Depressive disorders	Anxiety disorders
	$49 billion	$52 billion
	Dementias	Low back pain

Chronic pain[7]	80%	$700 billion
	Of chronic pain population cannot work	In lost wages and healthcare utilization

Major depressive disorder[8]	38%	$326 billion
	Increase in cost since 2010	Cost per year
		35% Direct costs of care
		61% Workplace costs
		4% Suicide-related costs

[1] World Health Organization, nd..; [2] Arias et al., 2022; [3] Davenport et al., 2020; [4] Sporinova et al., 2019; [5] Abramson et al., 2024; [6] Dieleman et al., 2025; [7] Young et al., 2022; [8] Fournier et al., 2021

ARPA-H

Today, mental health measurement is rare and inconsistent

126 different assessments screen and diagnose for 10 different disorders[1]

Disorder	#tools	#items	List of assessments
Depression	19	369	*Adult:* APA-Dep-A, BDI-II, CES-D, CESDR, EPDS, GDS-LF, GDS-SF, HAMD, IDS, MADRS, PHQ9, QIDS, ZDS, *Peds:* APA-Dep-C, CDI2, CESDC, MFQ, MFQS, RADS2
Anxiety	13	483	*Adult:* APA-Anx-A, BAI, GAD7, HAMA, LSAS, SPIN, STAI, ZAS, *Peds:* APA-Anx-C, MASC, RCMAS, SCARED, SCAS
PTSD	9	376	*Adult:* APA-PTSD-A, CAPS-5, PC-PTSD-5, PCL-5, PSS-SR5, SPRINT, *Peds:* APA-PTSD-C, CAPS-5-CV, CPSS-V
Bipolar/Mania	5	90	*Adult:* ASRMS, HCL32, ISS, MDQ, YMS
OCD	8	330	*Adult:* DOCS, FOCI, OCI-R, PI-WSUR, VOCI, Y-BOCS, *Peds:* CY-BOCS, OCI-OV
Addiction	13	319	*Adult:* ADS, ASI-5, ASSIST-3, AUDIT, CAGE, DAST-10, DAST-20, DUDIT, MAST, OCDS, SMAST, TWEAK, *Peds:* CRAFFT
ASD	22	1213	*Adult:* AAA, AQ-A-10, AQ-A, BAPQ, EQ-A, SQ-A, *Peds:* ADI-R, AQ-Adol-10, AQ-Adol, AQ-C-10, AQ-C, ASSQ, CARS2-HF, CARS2-ST, CAST, EQ-Adol, EQSQ, GARS-3, M-Chat, SCQ, SQ-Adol, SRS2
ADHD	9	418	*Adult:* ASRS-5, ASRS-Checklist, CAARS, DIVA 2.0, WURS, *Peds:* APA-Inatt, Connors 3, DBDRS, NICHQ
Schizophrenia	6	136	*Adult:* BPRS, CGI-SCH, NSA-16, PANSS, SANS, SAPS
Eating disorder	6	230	*Adult:* BITE, EAT-26, EDDS, EDE-Q, EDI-3, SCOFF
Cross-category	16	6190	*Adult:* APA-CC-A, BSI, CIDI CAPI, K10+, MINI, PROMIS-Profile-A, PROMIS-QB-A, SCID-5-CV, SCL-90-R, *Peds:* APA-CC-C, CBC, DISC-IV, KSADS-PL-5, PROMIS-Profile-C, PROMIS-QB-C, SDS

- Clinicians find questionnaires **limited**, **labor-intensive**, **error-prone**, and **subject to bias**[2-3]
- **<20%** of clinicians use measurement-based care in practice[4]

- **29-58%** of items overlap within questionnaires for the same disorder[1]
- Limited to no consistency assessing time periods across disorders

[1] Newson et al., 2020; [2] Bradford et al., 2024; [3] Horwitz et al., 2023; [4] Aboraya et al., 2018

ARPA H

What do we need measurement to look and feel like?

Continuous Glucose Monitors (CGMs) shifted the paradigm for diabetes care by giving people direct **access** to **actionable information** in **real time** for a **causal biomarker** for the disease.

What is the equivalent of a CGM for mental and behavioral health?

- ✓ **Accessible**
  - How does this integrate into a person's life?
  - How does this integrate into a clinician's practice?
- ✓ **Actionable**
  - Clear enough to indicate the direction to take
  - Reliable enough to change the course of treatment
- ✓ **Real-time**
  - At the speed of relevance for decision making
  - Time scale and delay may be less demanding than diabetes, perhaps daily or hourly
- ✓ **Causal**
  - Able to predict (with some fidelity) downstream disease effect, with a chance for intervention

Success enables:

- Quick changes to the course of treatment when it isn't working
- Prevention of downstream compounding effects from chronic disease

A first approximation of ground truth can be created from bio-psycho-social root of behavioral health and illness.

Validated measures exist that capture key elements of behavioral health.

Biological

Downstream physiological effects of behavioral health indicate when the body is under physical, mental, and/or emotional strain (e.g., **HRV, SOL**)

Psychological

Subjective elements of behavioral health (e.g., **Flourishing, PHQ-9**, **GAD-7**)

Social + Environmental

Changes in **homestay** are correlated with depression and social connection
Environmental changes have day-to-day impact (e.g., **travel**, **weather**)

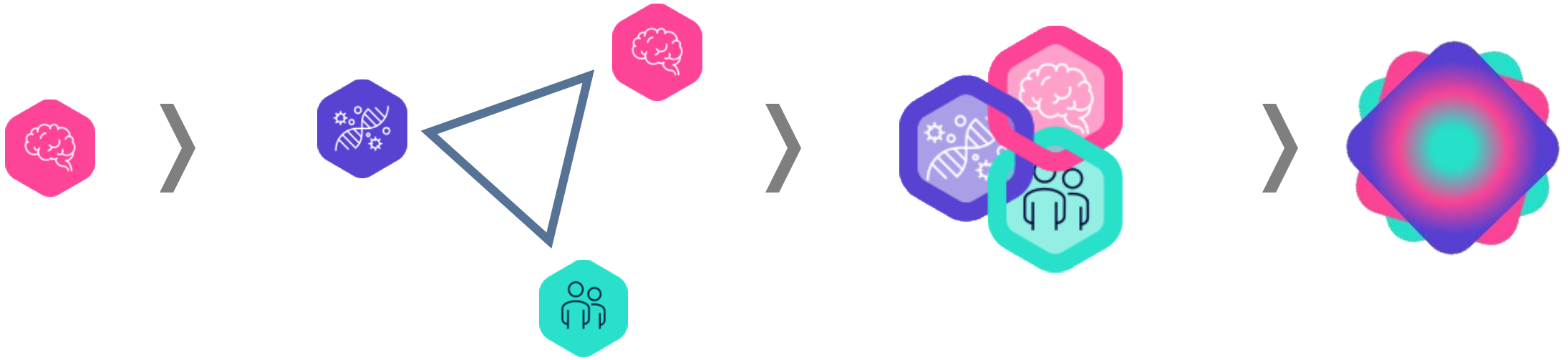
These measures are largely independent of one another, providing the opportunity for **convergent evidence of wellbeing,** somewhat robust to single dimension measures.

Alignment in time of uncorrelated measurements provide some plausibly robust indication of "Well" and "Unwell" moments.

When independent measurement of bio, psycho, and social components indicate the same direction, we can assume some confidence, e.g., **"Good days" and "Bad days".**

Triangulation of these measures forms a first draft of ground truth, rooted in biopsychosocial aspects of symptoms and wellbeing, and measurable with technology widely available today.

Development of effective and widely adopted mental health measurement will be progressive and compounding, with intermediately useful milestones.



EVIDENT

Evidence-Based Validation & Innovation for Rapid Therapeutics in Behavioral Health

Nate Mohatt, Ph.D.

Program Manager,
Proactive Health Office (PHO)

ARPA-H

Emerging, rapid-acting treatments

The New York Times

Seeking Relief From Brain Injury, Some Veterans Turn to Psychedelics

Unable to find effective treatments at home, veterans with brain-injury symptoms are going abroad for psychedelics like ibogaine that are illegal in the U.S.

https://www.nytimes.com/2024/12/16/us/psychedelic-ibogaine-veteran-brain-injury-ptsd.html

What if we had widely adopted objective measures for mental health and wellbeing?

EVIDENT will kickstart objective behavioral health measurement

Current behavioral healthcare lags far behind the need and scientific opportunity

Treatments are often inaccessible or ineffective

- 50% of people go untreated[1]

Treatment outcomes are suboptimal

- 30% of depression patients are "treatment resistant"[2]
- 40-60% of people treated for substance use relapse within a year[3]

Routine measurement can improve outcomes

- Fewer than 20% of providers use it[4]
- Diagnostics and management rely on self-report
- "Trial-and-error" treatment is the norm[5]

There are **no predictive, scalable, objective, standardized measures** of behavioral health

We don't know what is working, when, or for whom

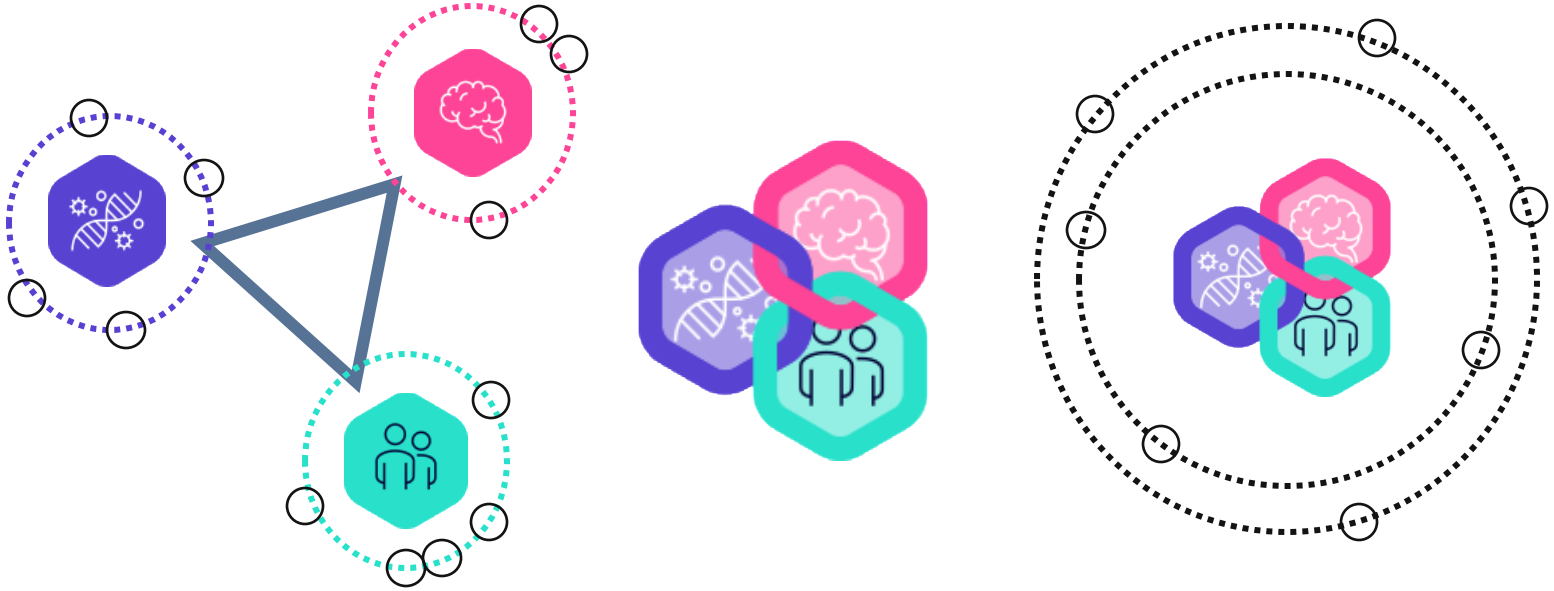
EVIDENT will:

- ✓ Identify likely candidates for **objective clinical endpoints** for interventions
- ✓ Accelerate **rapid, personalized, and durable** mental and behavioral health treatment

[1] National Academies of Sciences, Engineering, and Medicine, 2024; [2] Zhdanava et al., 2021; [3] National Institute on Drug Abuse, 2020; [4] Aboraya et al., 2018; [5] Kern et al., 2020

EVIDENT is the first step towards widely adopted objective measurement of mental health

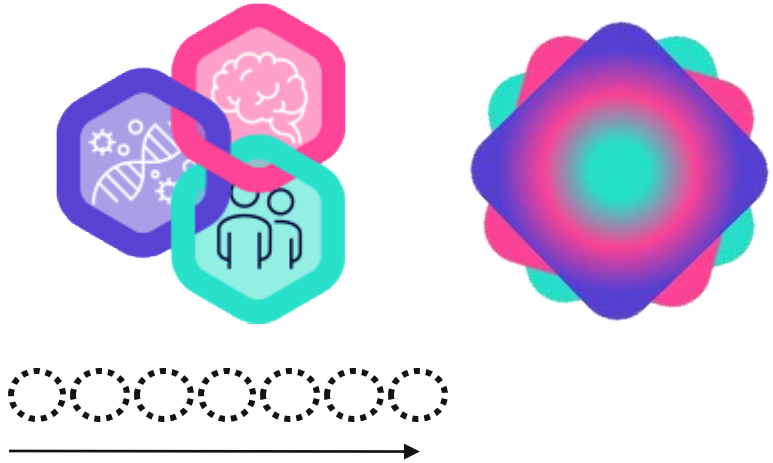
EVIDENT



Taken together, the data from EVIDENT will:

- **Establish which biomarker(s) might best predict** subjective & objective aspects of behavioral health, at minimum replacing unreliable and impractical self-report elements
- **Provide a quantitative approach** to select biomarker(s) for future causative studies
- **Act as a Rosetta Stone** for comparing wide variety of datasets & findings within behavioral health

Future



If EVIDENT is successful, data will be available to enable future efforts. For example:

- **Establish causal biomarkers**
- Optimize **predictive capability** (in accuracy and time)
- **Improve integration** into user life, clinician practice, and/or automated systems (e.g., machine learning or AI)
- Impact to **downstream physical health**

ARPA-H

Technical Areas

TA1 Objective Measurement of Clinical Change

TA2 Mechanisms of Rapid, In-Session Change

TA3 Personal Risk & Durability Profiles

TA4 Clinical Trial Data & Biosamples

Exploratory

- **Fixed $4 million over max 24 months per TA**

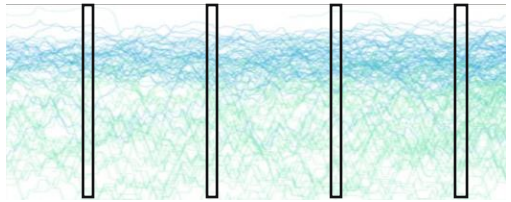
Contribute to Data Repository

- Calculated $ amount by data provided by performer

ARPA-H

TA1: Objective Measurement of Clinical Change

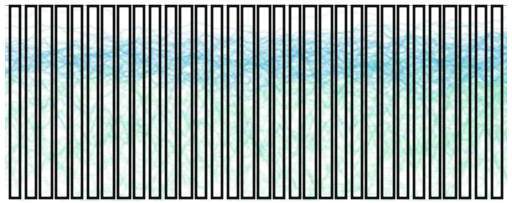
Challenge: Clinical endpoints are subjective and lack temporal granularity



Rate of change is greater than measurement frequency

Rapid-acting interventions require rapid, objective measurement

Solution: Real-time, biological, digital, and physiological biomarkers of rapid clinical effects

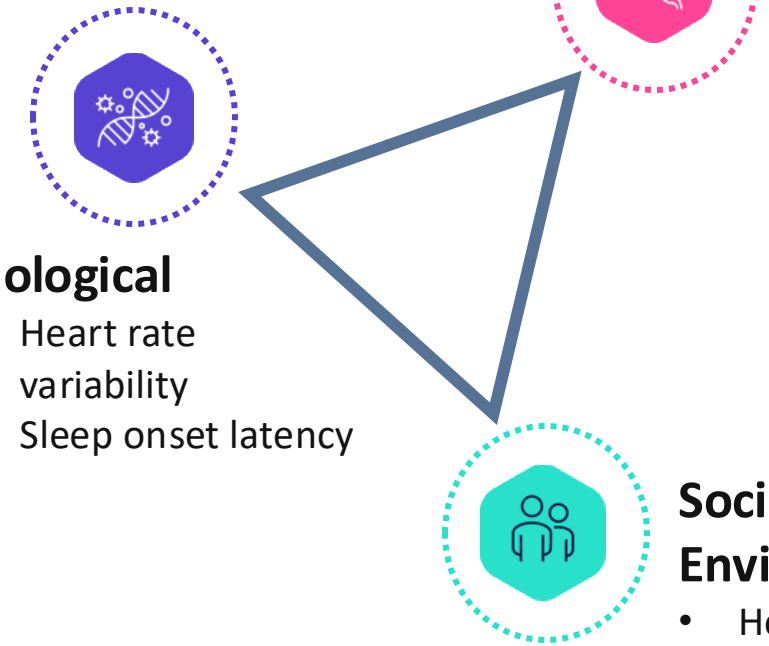


Measurement is frequent enough to be relevant

TA1 Goal

Likely candidates for continuous, minimally invasive, scalable indicators of behavioral health

TA1: Data of interest includes, but is not limited to:



Biological

- Heart rate variability
- Sleep onset latency

Psychological

- Patient Health Questionnaire (PHQ-9)[1]
- General Anxiety Disorder-7 (GAD-7)[2]
- Depression Anxiety Stress Scale-8 stress items (DASS-8)[3]
- Brief Resilience Scale (BRS)[4]
- Flourishing Scale[5]

Social + Environmental

- Homestay

- Biopsychosocial measures are **required** for new data collection
- FDA clinical endpoints are strongly preferred

Digital health

Brain Imaging

Neurotropic Factors

Oxidative/Cellular Stress

Metabolic Markers

Inflammation

Hormones

Positive/Negative Affect

Travel and Weather

See Table 1 in Request for Solutions (RFS) for more detailed information. Other relevant data may be considered.

[1] Kroenke et al., 2001; [2] Spitzer et al., 2006; [3] Ali et al., 2021; [4] Smith et al., 2008; [5] Diener et al., 2010

TA2: Mechanisms of Rapid, In-Session Change

Challenge: Impact of therapeutic session context is unknown

What is happening for the **person in the moment**?

What is happening between the **person and the facilitator**?

What are the ideal **environmental conditions**?

Solution: Capture session-related data from patients, facilitators, and/or the environment

- Before, during, and after session (e.g., debrief)
- Unobtrusive sensors (e.g., wearables)
- Comfortable, wireless EEG
- Behavioral analytics
- Setting, lighting, temperature
- Others

TA2 Goal

Individual-, dyadic-, and environmental predictors of effectiveness

EEG: electroencephalogram

TA3: Personal Risk & Durability Profiles

Challenge: Trial-and-error treatment approaches exacerbate suffering and illness

Who is at-risk for an **adverse event**?

Who is most likely to **respond** well to this treatment?

Which intervention is most **durable** for this person?

Solution: Advanced analytics of multimodal data to develop predictive, personalized models

- Biopsychosocial measures
- Digital health data
- Clinical data
- Genetics
- Biomarkers
- And/or other proposed data sources

TA3 Goal

Actionable insights for:

✓ Risk mitigation,
✓ Treatment-matching, and
✓ Monitoring

Exploratory TA Requirements (TAs 1–3)

Data collected in the context of **emerging, rapid-acting intervention research***

Neuroplastogens	Ketamine, ibogaine, scopolamine, psilocybin, dimethyltryptamine (DMT), lysergic acid diethylamide (LSD), and others
Neuromodulation	Transcranial magnetic stimulation (TMS), transcranial electrical stimulation (tES), focused ultrasound, transcutaneous vagus nerve stimulation (tVNS), and others
Digital Therapeutics	Virtual reality, smartphone apps, and others

*Intent is to focus on rapid-acting treatments, but strong proposals working with other types of intervention data may be considered

- ✓ Prior evidence of safety in humans (e.g., phase I clinical trial)
- ✓ Prior evidence of producing rapid clinical effects (e.g., within 1-2 weeks)

Data collection should **supplement existing protocols**; awards are not intended to fund brand new studies

- ✓ Complete IRB protocol required, either approved or under review at time of Solution Summary submission
- ✓ Proposed IRB amendments for supplemental data collection and/or analyses required by awardees at kick-off

Methodologies	Clinical trials, observational studies, regular clinical practice settings, and others

IRB: Institutional Review Board

Exploratory TAs: In-Scope Activities

- ✓ Thoughtful inclusion of Veterans as well as broader groups
- ✓ Intervention research targets behavioral health symptoms (e.g., preclinical, subclinical, mild-to-moderate) and/or behavioral health disorders (e.g., anxiety, depression, substance use disorder, PTSD)
- ✓ Proposals to analyze existing data collected in the context of emerging, rapid-acting intervention research including neuroplastogens, neuromodulation, digital therapeutics or other compelling interventions
- ✓ Proposals to collect and analyze new data collection supplementary to existing study protocols
- ✓ Collection of supplemental data from a subset of enrolled participants, from entire study samples, during planned or new follow-up assessments, and/or from intervention, control, and/or healthy participants
- ✓ Proposals limited to existing IRB protocol modification or amendment
- ✓ Data collection in the context of existing clinical trials (e.g., already planned, registered, or on-going, recruitment started or not yet started)
- ✓ Data collection outside the context of clinical trials (e.g., observational studies, regular clinical settings)
- ✓ Adult populations (≥ 18 years old)

PTSD: posttraumatic stress disorder

Exploratory TAs: Out-of-Scope Activities

- Data collected outside the context of behavioral health interventions
- No prior evidence of safety in humans (e.g., no prior phase I clinical trial)
- No inclusion of human subjects (e.g., simulations, models, animal studies)
- Brand new clinical trials (e.g., no existing protocol)
- Brand new development/testing of new therapeutic devices or new interventions (e.g., no existing protocol)
- New human subjects research requiring new IRB protocols rather than an amendment or modification
- Data collection from pediatric populations (< 18 years old)

TA4: Clinical Trial Data & Biosamples

Challenge: Lack of standardized, multimodal, longitudinal data collected during rapid-acting clinical trials limits scientific discovery

Solution: Collect standardized biopsychosocial data—plus biospecimens—across multiple ongoing rapid-acting interventional clinical trials.

- No technical volume
- Eligibility and conformity
- Rolling submissions

TA4 Goal
Standardized, multimodal, longitudinal data, curated and harmonized for future scientific discovery

[1] Newson et al., 2020

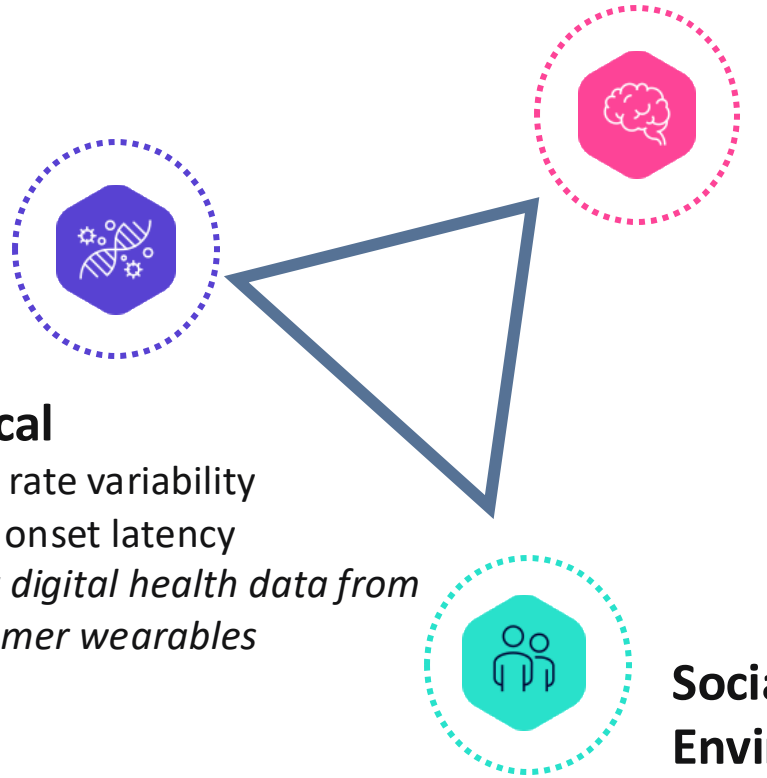
TA4: Eligibility

- ✓ A registered, interventional clinical trial (registration website, protocol number).
- ✓ Tests either: 1) a neuroplastogen, or 2) an accelerated neuromodulation treatment (specify).
- ✓ Treatment has demonstrated safety in humans (phase I clinical trial protocol number or equivalent).
- ✓ Treatment has demonstrated rapid effects for mental or behavioral health symptoms or disorders (within 1-2 weeks).
- ✓ Trial collects data on one or more FDA-approved clinical endpoints.
- ✓ A complete IRB protocol, approved or under review (protocol and submission status documentation required).
- ✓ Collect **essential data** at baseline, ~1 week, and ~3-months post-treatment.
- ✓ Accepts data submission requirements and data rights.
- ✓ Data collection to begin no later than **1 OCT 2026.**
- ✓ Accepts all terms and conditions in CX Hub Base Agreement; will become a CX Hub Consortium Member.

Ineligible

- Other types of interventions.
- Interventions without demonstrated safety.
- Interventions without demonstrated rapid effects for mental/behavioral health symptoms or disorders.

TA4: Essential Data Collection



Psychological

- Patient Health Questionnaire (PHQ-9)[1]
- General Anxiety Disorder-7 (GAD-7)[2]
- Depression Anxiety Stress Scale-8 stress items (DASS-8)[3]
- Brief Resilience Scale (BRS)[4]
- Flourishing Scale[5]
- **FDA Clinical Endpoints**

Biological

- Heart rate variability
- Sleep onset latency
- *Other digital health data from consumer wearables*

Social + Environmental

- Homestay
- *Other GPS data from consumer wearables*

Timing

Required

Baseline (pre-treatment)

~1-week post-treatment*

~3-months post-treatment

Optional

6-months post-treatment

12-months post-treatment (requires 6-months as well)

TA4: Optional Add-On Biospecimen Collection

Biospecimens*
Blood
Saliva
Stool
EEG

Timing
Baseline (pre-treatment)
Plus, *one or more* of the following:
< 24 hours post-treatment
Post-treatment timepoint 1
Post-treatment timepoint 2
Post-treatment timepoint 3

Add-on post-treatment timepoints are flexible and defined by performers to align with existing protocols.

*Standard Operating Procedures (e.g., processes, amounts, storage, shipping) are forthcoming.

TA4: Calculating Data Collection Costs

Instructions: Enter the number of participants planned for each type of data collection at each time point in the yellow-highlighted cells. Costs per participant are fully loaded and include reasonable costs for indirects.

All performers must collect Essential Data Collection at baseline (i.e., pre-treatment) and approximately 1 week and 3-months post-treatment.

Essential Data Collection (Baseline, ~1 Week, ~3 Months)	Cost Per Participant	# of Participants	Total Cost
Consenting + Devices	$ 2,686		$ -
Data Collection (Baseline, ~1 Week, ~3 Months)	$ 1,492	0	$ -
Subtotal Essential Data Collection			$ -

Performers may choose to extend Essential Data Collection to 6 months or 12 months post-treatment. The 6-month extention is required for the 12-month extension.

Extended Essential Data Collection	Cost Per Participant	# of Participants	Total Cost
Extra Timepoint - 6 Months	$ 1,297		$ -
Extra Timepoint - 12 Mor			
Subtotal Extended Esse			
Total Essential Data Col			

Performers may choose to add-on biospecimen collection to Essential Data Collection. Total number of participants for biospecimen collection cannot exceed total number of participants for Essential Data Collection. At minimum, biospecimens must be collected at baseline (i.e., pre-treatment) and [illegible] one or more additional post-treatment timepoints. Specify extra timepoints in the orange-highlighted cells.

Add-On Data Collection - Blood	Cost Per Participant	# of Participants	Cost	Specify Extra Timepoint(s) (e.g., 1-month post-treatment)
Add-On Blood - Baseline (Required for Add-On Blood)	$ 1,729		-	
Add-On Blood - One or More Follow-ups Required				
Add-On Blood - <24 Hours Post Treatment	$ 1,729		$ -	
Add-On Blood - Extra Timepoint 1 (Specify)	$ 1,729		$	
Add-On Blood - Extra Timepoint 2 (Specify)	$ 1,729		$ -	
Add-On Blood - Extra Timepoint 3 (Specify)	$ 1,729		$ -	
Subtotal Add-On Blood			$ -	

Maximum number of participants

May be fewer participants, but not more than the maximum number

TA4: Milestone Payment Calculator

Milestones					
The milestones and deliverables listed below are required for all awards. Months indicated represent the latest allowable completion dates ("no later than" deadlines). Entities are encouraged to submit all data and successfully accomplish the project on an accelerated schedule whenever possible.					
Month	**Task 1. Regulatory Preparation and Compliance**	**Task 2a. Collect Essential Data Task 2b. Collect Add-On Data**	**Task 3. Deliver Data to Data Repository**	**Payment**	**Explanation**
1	Kick-Off Meeting; Submission of Amendments to Approved IRB Protocols	Review SOPs	Review SOPs	$ -	25% of Consenting + Devices
3	IRB Approval for Data Collection; FDA Approval for Data Collection (as applicable); Data Sharing Agreements in Place; Submit All Monthly Reports	N/A	N/A	$ -	75% of Consenting + Devices
6	Submit All Monthly Reports	10%	>80%	$ -	10% of Remaining Costs
9	Submit All Monthly Reports	20%	>80%	$ -	10% of Remaining Costs
12	Submit All Monthly Reports	40%	>80%	$ -	20% of Remaining Costs
15	Submit All Monthly Reports	60%	>80%	$ -	20% of Remaining Costs
18	Submit All Monthly Reports	80%	>80%	$ -	20% of Remaining Costs
21	Submit All Monthly Reports	90%	>80%	$ -	10% of Remaining Costs
24	Submit Final Report	>90%	100%	$ -	10% of Remaining Costs
			Total	**$ -**	
			Balance Remaining	**$ -**	

Automatically Populates based on Data Collection Worksheet numbers

Performer Expectations

Collaboration among performers within and across TAs is strongly encouraged to ensure interoperability of data, methodological and regulatory alignment, and collective learning, but **collaboration is not mandatory.**

Participation is required in coordination meetings and events such as: program kick-off, virtual monthly status meetings, quarterly hybrid technical exchanges (TAs 1-3 only), 12-month ARPA-H review, and a final close out meeting.

Ensure all milestones are completed and documentation is submitted on-time; TA4 performers must begin collecting data no later than October 1, 2026.

Maintain all regulatory documentation, IRB protocols, and data sharing agreements throughout the period of performance.

Contribute deidentified data, biospecimens, and supporting documentation (e.g., data dictionaries, code) to the ARPA-H designated Data Repository.

Timeline

In Person & Virtual Proposers' Day
Dec 10, 2025

Announcement
Nov 21, 2025

Proposals Due
Dec 22, 2025

Pitch Invitations
Jan 2026

Kickoffs
Apr 2026

NOV | DEC | JAN | FEB | MAR | APR

2025 2026

Solicitation Launch
Nov 24, 2025

ARPA-H Reviews Submissions
Jan 2026

Invitation to Negotiations
Feb 2026

Awards to Successful Performers
Mar 2026

Pitch Week
Feb 2026

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For more information on:

EVIDENT

Please visit arpa-h.gov

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DECEMBER 10, 2025

Request for Solutions

ARPA-H-CXHUB-26-109 and ARPA-H-CXHUB-26-110

Caitlin Burns
Agreements Officer, Business Innovation Division

Approved for Public Release: Distribution Unlimited

Overview

ARPA-H-CXHUB-26-109

Technical Areas 1-3

- Technical Area 1: Objective Measurement of Clinical Change
- Technical Area 2: Mechanisms of Rapid, In-Session Change
- Technical Area 3: Personal Risk and Durability Profiles
- Solution Summary --> Pitches --> Award

- Submission Portal opens Dec 11, 2025

ARPA-H-CXHUB-26-110

Technical Area 4

- Essential Data Collection
- Add-On Biospecimen Collection
- Rolling Submission
- Fixed Price per Participant
- Award Application Package --> Compliance/Eligibility --> Award

- Submission Portal is open now

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ARPA-H

Request for Solutions (RFS)

ARPA-H-CXHUB-26-109

Technical Areas (TAs) 1-3

ARPA-H-CXHUB-26-109 (TAs 1-3) Highlights

- Solution Summaries are required
- Invitation to Pitch
- One Solution Summary per TA
- Fixed amount of $4M per TA award
- Maximum period of performance of 24 months
- ARPA-H will direct ATI to issue award (will still be an ARPA-H project)
- Negotiable Statement of Work

Solution Summaries

- Due December 22, 2025, by 1pm Eastern
- One Solution Summary for each Technical Area
- All conforming Solution Summaries will be evaluated IAW the Request for Solutions
- Select submissions will be invited to Pitch
- Submission portal opens December 11, 2025

Entity Eligibility Information (see Section 4 of RFS)

- No awards will be made to FFRDCs at either the prime or sub level
- SAM.gov Unique Entity ID is required for award
    - New submissions can take significant time
- Non-U.S. Entities See Section 4

Submission & Selection Overview (See Section 5 of the RFS)

Solution Summary

- Solution Summaries are mandatory
- Not to Exceed (NTE) six (6) pages
- Follow guidance in Appendix A
- Submitted via ATI's submission system
- Notification of invitation to Pitch will be sent via email. No further feedback will be provided

Pitch

- Informed via email of designated date and time
- Submission documents due one week prior to assigned Pitch
- 15-minute presentation, 30-minute Q&A
- Virtual or in person

Request for Solutions (RFS)

ARPA-H-CXHUB-26-110

Technical Area 4

ARPA-H-CXHUB-26-110 (TA 4) Highlights

- Rolling Submissions
  - Submission portal is open
  - Submissions will be accepted until funds are expended
- Fixed award amount based on number of participants
- Maximum period of performance of 24 months
- Fixed Statement of Work
- ARPA-H will direct ATI to issue award (will still be an ARPA-H project)

Eligibility Information (see Section 4 of RFS)

- No awards will be made to FFRDCs at either the prime or sub level
- SAM.gov Unique Entity ID is required for award
    - New submissions can take significant time
- Non-U.S. Entities See Section 4

Submission & Selection Overview (See Section 5 of the RFS)

Award Application Package

Packages reviewed in order of receipt for compliance and eligibility.

**Submission portal is open*

Award

If deemed compliant and eligible, awards will be initiated based on:

- Fixed Statement of Work
- Fixed price award amount based on the Data Collection Cost Worksheet (Appendix D) with fixed per participant pricing

Final Guidance

Nothing discussed today should be construed as amending the RFS. The final RFS is binding until/unless changes are posted.

Ask questions to arpa-h-cx-hub@ati.org after checking posted FAQs.

Register for a UEI in SAM.gov as early as possible.

Read the RFS.

ARPA H

For more information on

EVIDENT

Please visit arpa-h.gov

EVIDENT

Evidence-Based Validation & Innovation for Rapid Therapeutics in Behavioral Health

Launched November 21, 2025

ARPA-H

What if we had widely adopted objective measures of mental health and wellbeing?

VISION

EVIDENT will develop more quantitative measures of mental and behavioral health to help usher in a new era of safe, tailored, cutting-edge diagnostics and treatments.

TECHNOLOGY FOCUS AREAS

- Objective Measurement of Clinical Change
- Mechanisms of Rapid, In-Session Change
- Personal Risk & Durability Profiles
- Clinical Trial Data & Biosamples

EVIDENT page on the Customer Experience Hub

https://www.customerexperiencehub.org/evident/

Customer Experience Hub Introduction

Mike Stebbins , PhD
SVP, Medical and Health Division

Sarah Bailey , MS
CX Hub, Program Manager II

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Customer Experience Hub
PART OF THE ARPANET-H HEALTH INNOVATION NETWORK

From Design to Delivery

The focus of the Customer Experience Hub is putting people at the center of ARPA-H programs and projects in every stage of design and development.

Applying human centered design principles to engage patients, providers, and other stakeholders to ensure that solutions developed are desirable, feasible and viable.

@custexperiencehub

@custexphub

Caution

The **ARPA-H-CXHUB-26-109 and ARPA-H-CXHUB 26-110 Request for Solutions** (RFSs) are the official source of information regarding the active solicitation.

If you act on information from **any** source other than the RFS, it is at your risk.

CX Hub membership is **required** for an award to be made.

To join the CX Hub, please visit https://www.customerexperiencehub.org/how-to-join/

EVIDENT: Technical Areas (TA) 1-3

ARPA-H-CXHUB-26-109

Key Dates

Item	Date
Request for Solutions (RFS) posted	21 NOV 2025
Proposers' Day	10 DEC 2025
Submission Portal Opens	11 DEC 2025
Questions Deadline	12 DEC 2025
Solution Summary Deadline	22 DEC 2025 1:00PM ET

EVIDENT: Technical Areas (TA) 1-3

ARPA-H-CXHUB-26-109

Required Submission Documents

Solution Summary Solution Pitch

- Solution Summary – One (1) Document in pdf format. Should NOT exceed 6 pages for a single technical area. The page limit is exclusive of cover page and references. Appendix A of the RFS is the required format.
- Proposers can submit to more than 1 TA but a separate Solution Summary is required for each technical area

EVIDENT: Technical Areas (TA) 1-3

ARPA-H-CXHUB-26-109

Required Submission Documents

Solution Pitch – Three (3) Documents

1. Statement of Work– word document. (Template will be provided)
2. Solution Pitch Deck- .pdf document. (Template will be provided)
3. Administrative and National Policy Requirements Document .pdf document. (Template will be provided)
    - Biographical Sketch
    - Current and Pending Support

EVIDENT: Technical Areas (TA) 1-3

ARPA-H-CXHUB-26-109

- **Stage 1, Solution Summary:** Proposers are invited to submit a Solution Summary using the format contained in Appendix A of this RFS. The program manager and their team will evaluate proposed solutions using the criteria listed in the RFS.

- **Stage 2, Solution Pitches:** Only proposers who are invited to stage 2 will be able to submit all required proposal documents. Selected Stage 2 proposers will utilize the templates provided to them.

- **Stage 3, Invitation for Collaborate & Negotiation (IC&N):** Upon completion of the Program Manager's evaluation, Proposer(s) will be notified of the final award decision.

Selected proposers must be a CX Hub Spoke before an award is made.

EVIDENT: Technical Areas (TA) 1-3

ARPA-H-CXHUB-26-109

- Scientific and technical merit
- Feasibility
- 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.

See section 5.2 of the RFS for information on the evaluation criteria.

EVIDENT: Technical Areas (TA) 1-3

ARPA-H-CXHUB-26-109

- Proposers should submit a **separate Solution Summary** for **each Technical Area** to which they wish to apply.
- Proposers may submit to multiple Technical Areas
- Only proposers who are invited to stage 2 may submit a **Solution Pitch**
- **Solution Pitch** templates will be provided later

EVIDENT: Technical Area (TA) 4

ARPA-H-CXHUB 26-110

- TA 4: Collection of Supplemental Data & Biological Samples in Existing Clinical Trials
- Funding will operate under a fixed-price, milestone-based funding structure in which payments are tied to completion of specific milestones and successful review by ARPA-H.
- The maximum total award amount is **$10 million.**

EVIDENT: Technical Area (TA) 4

ARPA-H-CXHUB 26-110

Required Submission Documents

Compliant Award Application Packages will include the following required documents: (5MB or lower).

1. Cover Page
2. Completed Eligibility Criteria Matrix
3. IRB Protocol
4. Proof of IRB Submission or Approval
5. Research Security Disclosures and Review Form
6. Biographical Sketch (for all Senior/Key Personnel) Template available at https://www.nsf.gov/bfa/dias/policy/nspm-33-implementation-guidance.
7. Current & Pending support (for all Senior/Key Personnel) Template available at https://www.nsf.gov/bfa/dias/policy/nspm-33-implementation-guidance.
8. Data Collection Cost Worksheet submitted as an Excel Spreadsheet

EVIDENT: Technical Area (TA) 4

ARPA-H-CXHUB 26-110

Key Dates

Item	Date
Request for Solutions (RFS) posted	21 NOV 2025
Proposers' Day	10 DEC 2025
Submission Portal Opens	24 NOV 2025
Questions Deadline	12 DEC 2025
Solution Summary Deadline	Until funding is expended

Administrative Notes For All Technical Areas

ARPA-H-CXHUB-26-109 & ARPA-H-CXHUB 26-110

- **Period of Performance** is not to exceed **24 months** for all Technical Areas.
  - There will be an annual Performance review.

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

How to Get a UEI and Register in SAM.gov

Step 1: Create a Login.gov Account

1. Go to SAM.gov and click **Sign in.**
2. Select **Create an Account**
3. Once signed in, you'll return to SAM.gov.

Step 2: Get a UEI (Unique Entity ID)

1. Sign in to SAM.gov via Login.gov.
2. Click Get Started → Get Unique Entity ID.
3. Enter your business's legal name and physical address.
4. Submit and receive your 12-character UEI (usually processed quickly)

Tip: A UEI is required even if you are only a subrecipient or not yet seeking federal contracts

Step 3: Register Your Entity (for Contracts or Grants)

1. From SAM.gov, click Get Started → Register New Entity.
2. Complete all sections: legal info, TIN/EIN, business type, NAICS codes, bank details, and points of contact.
3. Review and submit. Registration is free and must be renewed annually.

Note: You only need full registration if applying directly for federal awards or contracts.

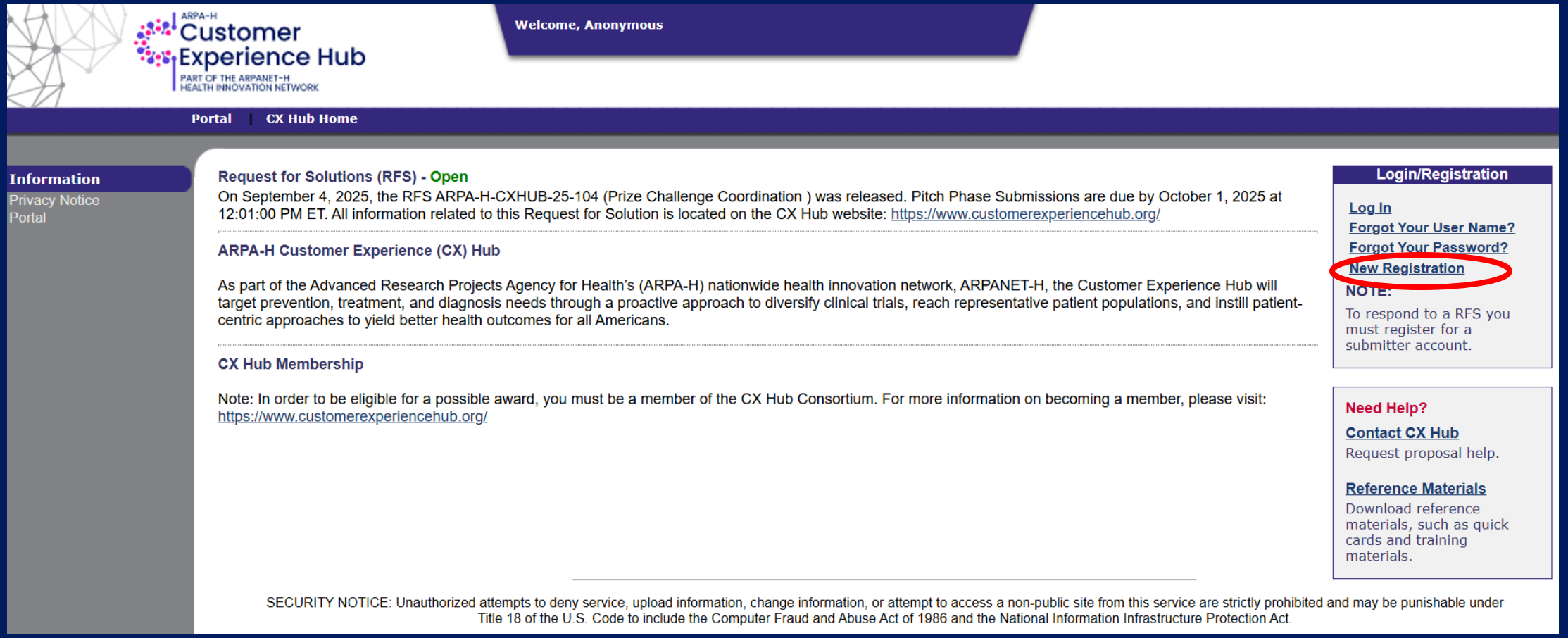
Before You Start – Gather This Information

- Legal business name & physical address
- Taxpayer Identification Number (TIN/EIN)
- Business type/structure (LLC, Corp, Nonprofit, etc.)
- Bank routing & account info (if paid directly)
- NAICS code(s) and point of contact details

BIDS Submission Guide

- Submissions will be submitted using the BIDS Platform: https://solutions.arpanet-h.org/CXHUB/BIDS.NSF/Start?ReadForm
- To respond to an RFS on BIDS, you first must register for a CX Hub BIDS account.
- After registering, you will then be able to submit a proposal to an open RFS.
- Step by step directions on how to submit a proposal are posted to the CX Hub Members Only Site and included as Appendix B to the RFS.

BIDS: New Registration



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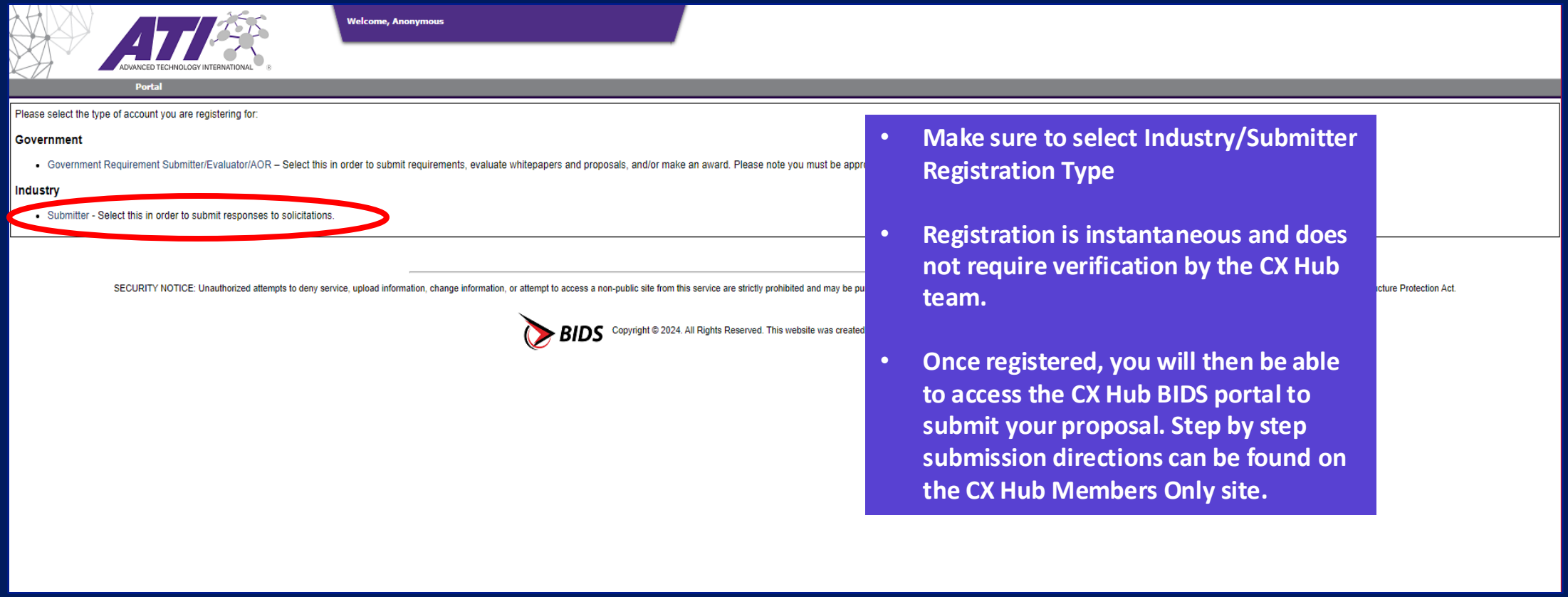
BIDS: New Registration



- Make sure to select Industry/Submitter Registration Type
- Registration is instantaneous and does not require verification by the CX Hub team.
- Once registered, you will then be able to access the CX Hub BIDS portal to submit your proposal. Step by step submission directions can be found on the CX Hub Members Only site.

Lunch Break
12:30 – 1:30PM

1:1 Discussions
Networking Break
1:30 – 2:30PM

Lighting Talks
2:30 – 4:30PM

Closing Remarks

Questions

- For inquiries on this RFS, please direct your correspondence to the following contacts:
  - Contractual questions related to this RFS should be directed to the CX Hub Contracts Manager, Alexis Hirr, 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
  - All questions should be submitted no later than December 12, 2025 by 5PM ET.

ARPA-H

Customer Experience Hub

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HEALTH INNOVATION NETWORK

Combradarie