These informational materials are updated as of Nov 16, 2026. Please reference the SPECTRA solicitation (SOL) documents for the most up-to-date information.

ARPA-H

SPECTRA

Systems for Phenotypic Evaluation, Clinical Trajectories, Response, and Agency

Technical Area (TA) 1: Multi-Factor Analysis and Trajectory Identification
TA2: Population-Scale Modeling and Data Integration

Program Overview and Proposer Briefing

Program Managers: **Russell Shilling, Ph.D., Yoram Vodovotz, Ph.D., and Erika Kim, Ph.D.**

TA1 and TA2 Solution Summaries due **Dec. 2, 2026, at 3 p.m. ET***

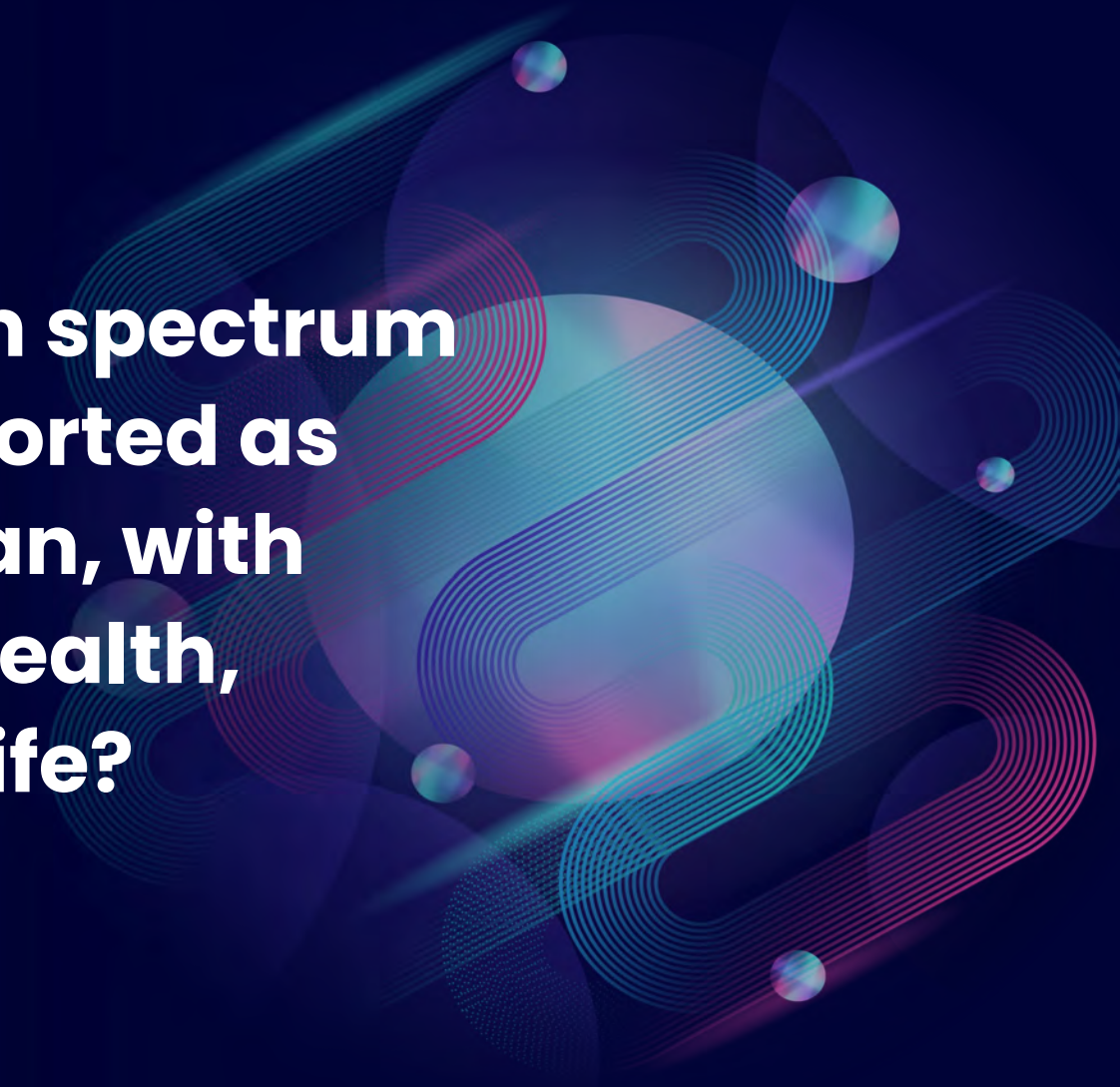
Approved for Public Release: Distribution Unlimited

**Deadlines subject to change. Please reference the solicitation documents for the most up-to-date information.*

WHAT IF

What if everyone on the autism spectrum could be understood and supported as an individual across the lifespan, with precision care that improves health, independence, and quality of life?

SPECTRA is designed to make this outcome possible.



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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 Department of Health and Human Services (HHS)
- No internal research labs; **disease agnostic**
- Generally, **fund outcome-based contracts,** not grants; accelerated award timelines
- Unique **U.S. Food and Drug Administration (FDA) reimbursement authority**



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

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



Term limits of three to six years bring urgency and idea flow.

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

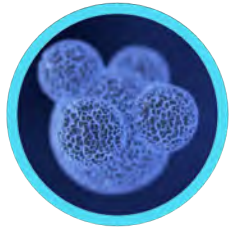


Bottom-up decision-making. Program Managers have autonomy to make decisions quickly.

ARPA-H is a problems-focused organization.

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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 program. PMs are empowered to stop underperforming projects.

Term Limits

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

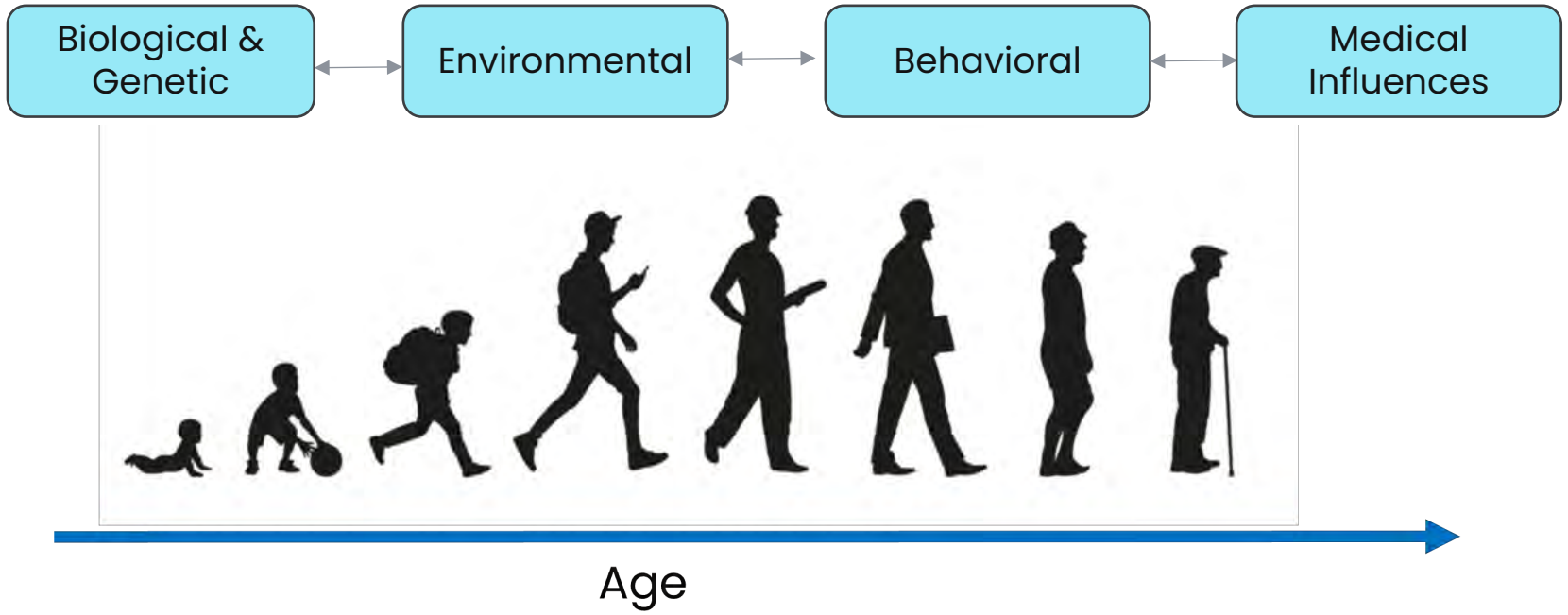
Success for ARPA-H is defined by real-world impact.

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PROGRAM GOAL

Autism as a complex event, not a single label

Factors that Shape Autism Spectrum Disorder (ASD) Trajectories



SPECTRA aims to understand the nonlinear interactions and exposures that lead to specific trajectories across the lifespan and translate those findings into precision care and assessments aimed at real-world environments outside the clinic.

1 in 31

U.S. 8-year-olds are identified with ASD.

Autistic people are valued members of families and communities, with diverse strengths, needs, and goals.

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TODAY'S CHALLENGE

Current care falls short in five ways for ASD

1. **Diagnosis comes too late.**
   We miss opportunities to intervene and prevent avoidable morbidity.

2. **Factors that influence development are studied in isolation.**
   Genetic, biological, immune, behavioral, environmental, and medical influences are examined separately.

3. **The data are siloed.**
   Records that could reveal trajectories cannot be linked across institutions.

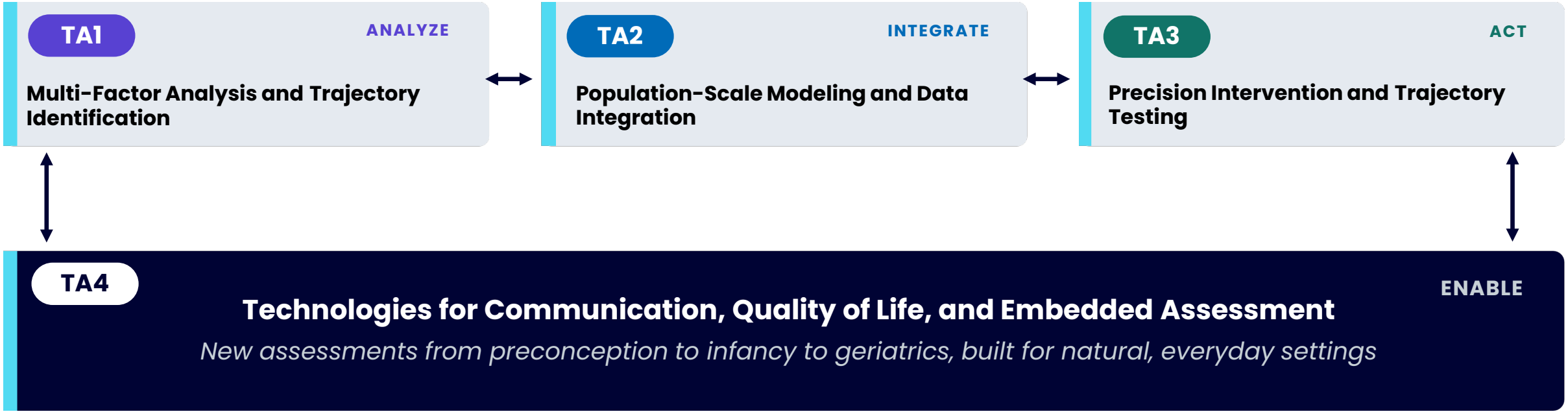
4. **Prediction and data do not drive care.**
   Even where data exist, prediction models do not capture the individual nature of development — let alone translate into meaningful guidance to inform care.

5. **Function is not measured in real-world settings.**
   Clinic-based assessment gives a limited view of daily communication and function.

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SPECTRA: Four technical areas, one system

Moving autism care beyond a single diagnostic label toward biologically and behaviorally informed, trajectory-guided treatment.



Note: SPECTRA is presently soliciting only solution summaries for TA1 and TA2, and proposals for TA4. The deadline for TA4 solution summaries has passed, and instructions for TA3 solution summaries will be released at a later date.

These informational materials are updated as of Nov. 16, 2026. Please reference the SPECTRA solicitation documents for the most up-to-date information.

TA1: Multi-Factor Analysis and Trajectory Identification

- TA1 identifies distinct, autism-related trajectories by integrating and analyzing comprehensive, multimodal data that resolve the interactions among genetic, epigenetic, immune, metabolic, microbiome, environmental, infectious, iatrogenic, and prenatal and perinatal factors — all domains usually studied separately.
- TA1 is an analysis area. Using new modeling on existing data, TA1 work begins in Year 1, and aims at causal, individual-level trajectory structure rather than single-factor association.
- TA1 teams should incorporate new data from all TAs, as appropriate for their proposed work, as these data come online.
- TA1 supplies the trajectory structure TA3 needs to stratify treatment.

Goals:

- Resolve nonlinear, time-dependent interactions among many factors, moving beyond association toward causal inference.
- Deliver first-generation candidate trajectory definitions in Year 1, with calibrated uncertainty and preregistered plans.
- Characterize trajectories at the individual level, with population coverage reported.
- Integrate validated TA4 real-world measures from Year 2 and re-estimate as the data enrich.
- Issue an annual statement of the measurement gaps that most limit trajectory resolution.

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TA2: Population-Scale Modeling and Data Integration

- TA2 is the data integration and federation backbone of SPECTRA.
- This technical area federates existing and newly generated data across institutions without moving records, applies common data standards and stringent quality control, and characterizes prevalence, incidence, and trends across the full range of autism-affected people and support levels.
- TA2 is built to enable secure, long-term access to longitudinal, multidomain data so the same people can be followed as they age. The federated network is designed to become self-sustaining national infrastructure that outlasts the program.

Goals:

- Map every federated source into a common data model built on standards such as Fast Healthcare Interoperability Resources (FHIR) and Observational Medical Outcomes Partnership (OMOP), extended to sensor, acoustic, eye-tracking, omics, and exposure data.
- Publish a privacy architecture with privacy-preserving linkage, federated learning at scale, differential privacy, and secure execution.
- Advance methods for measurement error, missing data, and differing ascertainment so heterogeneous data combine validly.
- Characterize who is and is not represented, bounding the generalizability of TA1 trajectories.
- Stand up an operating federated network of live nodes built to persist beyond the program.

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TA3: Precision Intervention and Trajectory Testing

- TA3 tests interventions within trajectories rather than against the autism label, establishing which options work for whom and using each trial as an experimental test of the mechanism it targets.
- Trials open with broad eligibility and add trajectory stratification as TA1 confirms trajectories, so a delay upstream slows refinement rather than halting the work.
- Priority goes to the co-occurring conditions that cause the most harm and are most often missed.

Goals:

- Run adaptive platform and sequential multiple-assignment trials under a master protocol with shared controls.
- Register in advance each arm's target, predicted effect, and the subgroups where the effect is and is not expected.
- Prioritize high-harm, co-occurring conditions — including when to safely reduce or stop medication — held to the same evidentiary standard.
- Measure outcomes in daily life through TA4 measures, with durability at 12 months as the bar.
- Codesign endpoints and meaningful benefit with autistic people and families.

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TA4: Technologies for Communication, Quality of Life, and Embedded Assessment

- TA4 develops technologies people want in daily life, across the lifespan, that generate assessment data as a byproduct of ordinary use.
- Example approaches include wearables, Augmentative and Alternative Communication (AAC) and speech interfaces, phones, camera-based movement analysis, eye-tracking on tablets, low-channel electroencephalogram (EEG), and immersive tools.
- Used daily, each approach yields continuous, ecologically valid measurement of domains assessed today only in the clinic and improves with use through personalization. Measurement, personalization, and sustained use are treated as one system.

Goals:

- Produce continuous, ecologically valid measurement outside the clinic, as a byproduct of use.
- Serve three returns at once: identification and characterization, therapeutic effectiveness, and device personalization.
- Solve cold start, few-shot personalization, nonstationary, adaptive drift, and on-device constraints.
- Codesign with the people who will use the technology from the earliest stage; acceptance and sustained use are the test.
- Deliver durable functional benefit at 12 months, with no loss of user agency.

Boundary. Measurement must come as a byproduct of use. A capability that requires a task to be performed in order to measure belongs in TA1. Addresses Limitation 5.

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SPECTRA TAs Are Interoperable and Not Executed Sequentially

- TA1 identifies candidate trajectories from the nonlinear interaction of many factors, using new modeling on existing data. It begins in Year 1 without waiting for new measurement.
- TA2 builds durable, secure infrastructure that integrates data across institutions and characterizes the population, serving every area.
- TA3 runs rigorous trials that act on trajectories, concentrating on the co-occurring conditions that drive the most harm.
- TA4 generates the real-world measurements TA1 and TA2 need, enriching them from Year 2 onward, and delivers support technologies that improve daily function.

TA1 ↔ TA4

Each other's answer key

TA1 models the trajectories worth measuring. TA4 builds the measurements to see them. Each phase of TA development sharpens the other, converging on both the outcomes that matter and the measurements to assess them.

Co-development by design, not circular logic.

These informational materials are updated as of Nov. 16, 2026. Please reference the SPECTRA solicitation documents for the most up-to-date information.

Planning to propose to both TA1 and TA2?

- **Separate Solution Summaries**: Groups may propose to both TAs, but these solution summaries must be submitted separately to each respective TA.
- **Combined TA1 & TA2 submissions *will not be accepted***.
- **Each submission must be workable independently**: Submissions to TA1 and TA2 from the same group are permitted, but these submissions must be independently feasible.
- **Submissions may synergize**: If submitting for both TAs, groups may briefly reference synergies offered between the two independent submissions.
- **Overlaps in scope will be negotiated**: Overlapping costs and efforts between TA1 and TA2 submissions from the same group may be separated/reduced/eliminated during contract negotiation.

Reminder: Proposers must apply to TA1 and TA2 **SEPARATELY**.

These informational materials are updated as of Nov. 16, 2026. Please reference the SPECTRA solicitation documents for the most up-to-date information.

Planning to propose to both TA1 and TA2?

To prepare a responsive submission, note the key technical differences between TAs 1 and 2. Proposers should refer to the SPECTRA Innovative Solutions Opening (ISO) for additional details.

Category	TA1: Analyze	TA2: Integrate
Scope	Produces ***individual-level*** patient trajectories and modeling to: 1. Identify gaps in biological understanding for hypothesis testing. 2. Discover causal connections.	Establish a federated network, common data model, identify gaps in large datasets, and analyze ***population*** characteristics such as incidence, prevalence, subgrouping, etc.
Core method	Causal/nonlinear interaction modeling based on SPECTRA data returns	Data federation and harmonization, privacy architecture, sustainability planning
Interface with SPECTRA TAs	Provides TA2 with testable trajectory definitions and hypotheses for population-scale analyses and enables patient stratification for TA3	Provides TA1 and TA3 with the analytic environment, harmonized cohort measures, and population-level analyses on how TA1 results differ from the broader population
Does NOT do	Build data infrastructure/standards or conduct *population-level* analyses	Conduct *individual* causal/mechanistic modeling

Note: Teams may submit to both TAs, but each submission must stand alone and be independently fundable. Submissions may note synergies, but neither submission may depend on or be a prerequisite for the other.

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TECHNICAL AREA 1

Turning Data into Trajectories

TA1 seeks to connect individual data with trajectories by:

1. Harnessing multimodal datasets that capture metabolic, genetic, infectious, environmental, and other factors.
2. Integrating those datasets to understand patient trajectories in a multifactorial way.

Trajectories can derive from interactions between many different types of data. Many of these data are collected and analyzed separately. TA1 aims to search for multimodal interactions that can explain an individual patient's autism trajectory.

From the outset: Relationships may be discovered that connect data in novel ways. The goal is to find and describe these interactions and how they influence patient trajectory.

These informational materials are updated as of Nov. 16, 2026. Please reference the SPECTRA solicitation documents for the most up-to-date information.

KEY DATES · TECHNICAL AREA 1

TA1 Solution Summaries first, then full proposals

STEP 1

Sept. 17, 2026

ISO issued

The SPECTRA ISO was posted.

STEP 2

Nov. 18, 2026

TA1 portal opens

TA1 Solution Summary submission opens at solutions.arpa-h.gov.

STEP 3

Dec. 2, 2026 · 3 p.m. ET

TA1 Solution Summaries due

Mandatory preproposal
Attachment A gives the format and instructions. ARPA-H reviews each and encourages or discourages a full proposal.

STEP 4

Date to be announced

TA1 Full Proposals due

Attachment B will give the proposal requirements and instructions. Proposers should heavily consider Solution Summary feedback before submitting.

Solution Summaries are mandatory. This slide is only for the TA1 submission. Monitor SAM.gov for amendments and the posting of each additional TA's preproposals and proposals.

Questions after this briefing: submit at solutions.arpa-h.gov/Ask-A-Question and select SPECTRA in the dropdown, or email SPECTRA@arpa-h.gov. General questions and answers are posted publicly.

Future dates are subject to change. Please reference the solicitation documents for the most up-to-date information.

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TA1 OBJECTIVE

Harness and connect existing data sources for novel insights

The main purpose of TA1 is to generate patient trajectory definitions and the interactions that give rise to them. Performers begin with existing datasets, cohorts, and biobanked samples to immediately begin assembling and connecting data. TA1 is inherently interdisciplinary, requiring analytic and computational methodologists to work alongside domain scientists across genetics, exposure science, immunology, metabolism, and developmental measurement.

EXAMPLE DATA TYPES MAY INCLUDE:

- Genetics
- Environmental
- Microbiome
- Metabolic
- Epigenetics
- Prenatal/Perinatal

Trajectories are built through connections. Using many types of data and building connections allows teams to build novel insights into patient trajectories. A goal is to break down barriers between the ways researchers connect these exposures to generate testable hypotheses that can describe patient experiences. TA1 builds novel connections rather than analyzing factors in isolation.

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One stream of data, three returns

TA1 exists to analyze data between previously unconnected fields to build novel insights into biological connections and patient trajectories. This process happens in three key steps:

1

Identify and examine complex interactions

Datasets that span a wide breadth of biological phenomena will be assembled, and interactions identified.

2

Apply assays where gaps in understanding exist

Where gaps exist, novel assays will be applied to gain greater understanding of patient data. Development of new technologies is not supported.

3

Generate candidate patient trajectories

Trajectories should be testable with defined uncertainty and be able to be delivered to other TAs for interrogation.

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CO-DEVELOPMENT

TA1 and TA4 are each other's answer key

TA1's problem

The models needed to interpret trajectories are nonlinear and incomplete.

TA4's problem

The real-world measurements needed to observe trajectories in daily life do not yet exist.

The co-development loop:

- TA1 defines and models the trajectories worth measuring, informing what TA4 builds.
- TA4 pushes novel real-world measurements that TA1 incorporates and tests against its models.
- Each round converges on both the outcomes that matter and the measurements to assess them.

Co-development by design, not circular logic.

The Interface: TA1 assembles and assesses data to build candidate trajectories and identifies measurable, actionable gaps to TA4. TA4 interrogates these gaps and returns results to TA1 to improve trajectory resolution.

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Requirements every solution must meet

These apply to every TA1 submission.

Leverage existing data/cohorts

Efforts to understand patient biology begin immediately, without the need for novel data acquisition. Performers should have identified existing datasets that can be combined and gaps that can be readily identified.

Integration of multiple datasets

Data must span multiple different fields of patient biology to build the novel interactions that guide trajectory generation. Efforts that focus on one type of dataset or exposure biology will fail to generate these new insights.

Move beyond causal inference

Disease biology is complex and nonlinear. Novel connections should interrogate beyond causal inference and can include sibling comparison, temporal ordering, negative controls, etc. Analysis plans must be able to be independently replicated and validated.

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Insights from Data: TA1 must build connections and understanding among data types

Multiple data types

Bridge connections between types of analyses

Nonlinear interactions

Connections between data may be nonintuitive

Individual characterization

Patient-level insights to inform individual trajectories

Independent verification

Observations can be replicated between different sites and groups

Noncausal inference

Observations are supported by negative controls, sibling comparison, temporal stamping, etc.

Personalized assessment to build personalized trajectories

Novel insights across data types build connections to explain a patient trajectory. These hypotheses are testable and guide other TAs to fill gaps.

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METRICS

Early Data Analysis to Discover Connections Rapidly

Proposals should identify available data resources and how those will be leveraged to build insights

- **Readily available data**: Data resources already exist and can be interrogated on Day 1.
- **Early trajectory identification**: Identify preliminary patient trajectories by Month 6.
- **Grounding of observations**: Patient trajectories should be comparable to nonautistic individuals.
- **Constant innovation**: Refined and new trajectories should be provided at six-month intervals.
- **Interaction hypothesis**: Define biomarkers or points of intervention.
- **Biomarker validation**: Use held-out or retrospective data to test and verify hypotheses.
- **Cross-TA Cooperation**: Identify key areas of uncertainty and translate those to TA4 for investigation.

Note: Proposers may submit their own performance metrics if technically justifiable for consideration by the PM.

How targets are set:

The program sets the overall goal of combining datasets in novel ways.

The performer proposes trajectories, the data used to describe them, and the biomarkers that can predict them.

TA1 metrics will be assessed at:

- **G1**: Month 3
- **G2**: Month 6
- **G3**: Month 12

G=Gate

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DELIVERABLES

Per-award and program-level

PER-AWARD DELIVERABLES

- **Multifactorial data analysis**: analysis across biological fields to understand connections between previously disconnected fields
- **Next-generation description of patient trajectories**: deep analysis of datasets to identify trends and trajectories that describe patient experience
- **Interactions that underlie patient biology**: identification of biomarkers or environmental factors that can be traced and intervened on to improve patient experience
- **Novel data types for cross-TA collaboration**: bounded and outcome-driven uncertainties translated for other TAs to interrogate

PROGRAM-LEVEL OUTCOMES

- **New technologies that improve outcomes**: at least three technologies demonstrating durable functional benefit at 12 months of use, spanning the communication and function continuum and the lifespan, from fluent speech with impairment through intermittent speech loss to no reliable expressive method
- **Demonstrated population transfer**: improvement in base-model performance for new users arising from federated learning across the cohort
- **Public benefit capabilities**: open-speech models, a consented and shareable speech corpus, and a public benchmark, released under open license and expected to outlast the program

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Out-of-Scope

- **Single-modality datasets**: analyses and/or datasets based uniquely on a single factor
- **Development of measurement devices**: novel devices, at-home measurement tools, or assistive devices are in TA4's remit
- **Construction of data infrastructure**: construction and facilitation of federated data systems is in TA2's remit
- **Risk prediction**: prenatal or perinatal observation to define future risks
- **Narrowly scoped needs assessment**: analyses or trajectories that exclude individuals with high support needs or without reliable speech

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Questions and how to propose

PROPOSING TO SPECTRA

- Proposers may submit to one or more technical areas. Submissions addressing a single technical area are welcome and expected.
- To respond to more than one TA, submit separate submissions when the submission portals open. Each must stand on its own should only one be funded and may note synergies if they exist.
- **TA1 Solution Summaries are due Dec. 2, 2026, at 3 p.m. ET.*** Follow the solicitation and Attachment A for required format.

*Deadlines subject to change. Please reference the solicitation documents for the most up-to-date information.

Questions and updates

- Submit questions at solutions.arpa-h.gov/Ask-A-Question and select SPECTRA. General questions and answers are posted publicly.
- Email the program at SPECTRA@arpa-h.gov.
- Monitor SAM.gov for amendments and the posting of each Technical Area's Attachment A and B.

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SPECTRA · TECHNICAL AREA 1

Turning Data into Trajectories



- Bring together a wide array of biological data to build novel understanding of patient trajectories.
- Define uncertainty that other teams can test.
- Improve understanding of patient trajectories.

Program Manager **Russell Shilling, Ph.D. and Yoram Vodovotz, Ph.D.**
TA1 Solution Summaries due **Dec. 2, 2026, at 3 p.m. ET***

*Deadlines subject to change. Please reference the solicitation documents for the most up-to-date information.

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TECHNICAL AREA 2

Population-Scale Modeling & Data Integration

TA2 aims to overcome limitations of siloed data to decode health trajectories by:

1. Building a longitudinal, multidomain federated data network as the backbone of all SPECTRA TAs.
2. Establishing an analytic environment where multimodal data can be analyzed to inform precision diagnosis and care.



These informational materials are updated as of Nov. 16, 2026. Please reference the SPECTRA solicitation documents for the most up-to-date information.

KEY DATES · TECHNICAL AREA 2

TA2 Solution Summaries first, then full proposals

STEP 1

Sept. 17, 2026

ISO issued

The SPECTRA ISO was posted.

STEP 2

Nov. 18, 2026

TA2 portal opens

TA2 Solution Summary submission opens at solutions.arpa-h.gov.

STEP 3

Dec. 2, 2026 · 3 p.m. ET

TA2 Solution Summaries due

Mandatory preproposal
Attachment A gives the format and instructions. ARPA-H reviews each and encourages or discourages a full proposal.

STEP 4

Date to be announced

TA2 Full Proposals due

Attachment B will give the proposal requirements and instructions. Proposers should heavily consider Solution Summary feedback before submitting.

Solution Summaries are mandatory. This slide is only for the TA2 submission. Monitor SAM.gov for amendments and the posting of each additional TA's preproposals and proposals.

Questions after this briefing: submit at solutions.arpa-h.gov/Ask-A-Question and select SPECTRA in the dropdown, or email SPECTRA@arpa-h.gov. General questions and answers are posted publicly.

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Building the infrastructure to overcome data silos

TA2 exists to build a durable, self-sustaining infrastructure to enable the future of precision care for autism by connecting fragmented data across healthcare systems and records.

1

SHARED INFRASTRUCTURE FOR SPECTRA TAs

TA2 has internal customers within SPECTRA and serves to enable the evaluation and success of other TAs.

2

FEDERATION AND HARMONIZATION

TA2 aims to federate existing and newly generated data across institutions without moving records while requiring stringent quality and privacy controls.

3

POPULATION-SCALE ANALYSIS AND METHODS

SPECTRA seeks advances in method, not only the application of existing methods to a new disease area.

The strongest submissions address all three components.

These informational materials are updated as of Nov. 16, 2026. Please reference the SPECTRA solicitation documents for the most up-to-date information.

TA2 OBJECTIVE

TA2's Shared Infrastructure has internal customers

The primary purpose of TA2 is not only to produce findings but to enable the other SPECTRA technical areas. A substantial share of TA2 milestones will be defined by whether TA1, TA3, and TA4 can execute against it.

Serves	TA2 must provide	Failure mode if not delivered
TA1	Harmonization of cohort measures, an analytic environment, and population-scale comparison against which cohort patterns are tested	TA1 patterns remain single-cohort findings and cannot be generalized
TA3	Trial-ready stratification, participant identification against eligibility criteria, and endpoint data drawn from routine care	Trials cannot open stratified arms and revert to unstratified enrollment
TA4	Federated learning substrate, telemetry ingestion in the common schema, and a versioned model registry	Device personalization cannot be validated, and TA4 cannot return data to TAs 1 and 3
External researchers	Documented access under governance, after the program's own use	The infrastructure does not outlive the program

Requirement: Every submission must explicitly state how and when the TA2 services become available for each TA by proposing a "capability ready by date" milestone.

These informational materials are updated as of Nov. 16, 2026. Please reference the SPECTRA solicitation documents for the most up-to-date information.

TA2 OBJECTIVE

Building the Capability: Federation & Harmonization

The Problem: Fragmented, siloed data across the population limits our understanding of how autism unfolds over the years.

The Goal: Federated data network that integrates existing and newly generated data across institutions that is financially sustainable after the program.

Objectives:

- Common data model that supports federated learning across both retrospective and prospective data
- Extension of the data model beyond observational health care data origins
- Privacy and technical architecture development to prevent reidentification of participant data
- Development of a plan to maintain the infrastructure of the network so that privacy posture is kept intact
- Codesign plans of governance, consent, data standards, and common data elements with the autism and data-contributing communities
- Demonstration of privacy-preserving record linkage across nodes and across time
- Node onboarding procedures that allow new node to join without performer engineering support

Requirement: Every submission must explicitly state how and when the TA2 services become available for each TA by proposing a "capability ready by date" milestone.

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Prioritizing Privacy of the Federated Network

Privacy & Trust by Design — Tested, Not Just Promised

Core Principles:

- No centralized repository — custodians are not expected to relinquish custody of their data
- Open source — privacy architecture specifications must be published when operational and not merely described

Privacy-Preserving Linkages

- Goal is to follow the same individual across nodes and across time
- Should be verified with sensitivity/specificity reported against a benchmark to assess and provide accuracy

Co-Governance & Design

- Networks must be codesigned with autism and data-contributing communities
- Network and privacy architecture should reflect the priorities and privacy expectations of those whose data it holds

Proof Is in the Pudding: Privacy Testing

Performer Responsibilities:

- Must design and build the privacy architecture and publish when operational
- Must declare specific adversary model at award and, if using differential privacy, must declare numeric privacy budget and accounting method
- Demonstrate privacy-preserving record linkage
- Cooperate with program-selected red team for recurring testing of privacy architecture

Program Responsibilities:

- Selects and conducts independent red-team testing of performers' networks
- Requires testing at least annually and after every major architecture change
- Metric: ZERO (0) successful reidentifications assessed at G2 and the final assessment

These informational materials are updated as of Nov. 16, 2026. Please reference the SPECTRA solicitation documents for the most up-to-date information.

Federated Analysis: No single site has the whole picture

Bar for Entry: Methodological advances required – standard supervised learning on assembled data is *not responsive*.

Required Analytic Capabilities:

Population characterization

Should describe prevalence, incidence, and trends across subgroups and support levels within the United States

Data-quality methods

Including measurement error, missing data and cross-source ascertainment differences so that heterogeneous datasets can be analyzed together

Federated modeling

Should be across nodes with heterogenous data where no single site holds all modalities

Representation analysis

Describes who is and is not represented in the federated data and describes how the TA1 cohort trajectories differ from the broader population

Full transparency

Explicit reporting of uncertainty, bias, subgroup performance, and failure modes (including where the models do not work)

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Federated Analysis: Proof of Value

Performers are expected to uphold values of transparency and validation for the federated network by:

1. **Reporting Everything — Including Failure**
   - Must publish methods with executable reference implementations to be useable beyond SPECTRA
2. **Prove Federation Was Necessary**
   - Each analysis must specify the inferential gain that federation provided compared to analyses at a single node
3. **Closing the Loop With TA1**
   - Conduct population-scale testing of TA1 candidate trajectory definitions with those results returned to TA1 and TA3 within a stated interval of receipt

Independent Validation & Verification

Program-selected IV&V partner will validate:

1. Analysis methods published by performers
2. TA1 trajectories using provided code and held-out data to verify performer-reported inferential gains
3. Published benchmark query sets covering cohort discovery, aggregate statistics, and federated model fitting

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TA2: Sustainability & Governance — Built to Outlive the Program

***The Mandate**: Federated network must become self-sustaining national infrastructure and not a program deliverable that disappears. Sustainability planning is a deliverable and not an afterthought; it should be developed and executed on a fixed timeline within the program.*

Required Commitments

To build a national infrastructure, a key TA2 deliverable will be developing a financial sustainability plan that includes:

1. Named host entity
2. Committed non-ARPA-H funding
3. Governance arrangements sufficient to operate the network for at least three years beyond the program

Governance Structure

The governance body of the network must include representatives of the data that it holds. Plans must include representation from autistic and data-contributing communities with an operational consent and revocation mechanism.

Sustainability and governance. Development and execution of this plan are expected to occur during program performance with (1) delivery of the plan by Month 24 and (2) execution of its commitments by Month 48.

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TA2 is executed in three phases across 46 months

Program Phase Reviews will occur at the end of each phase

Phase 1: Federate & Demonstration of Privacy Architecture

Objectives include executed data use agreements; a live cross-node query on real data; common data model version 1.0 published with crosswalks; privacy architecture and adversary model declared and published; an analytic environment available to TA1 performers by Month 9; and the full-service schedule for SPECTRA TAs baselined by Month 3.

Phase 2: Scale & Serve

Objectives include node growth and diversification beyond electronic health records and claims, field-level harmonization against the baselined source list, on-time service to TA1, TA3, and TA4, first population characterization, model registry in operation, methods submitted for peer review, and external access exercised.

Phase 3: Operate, Open & Sustain

Objectives include full-scale operation, node onboarding without performer assistance, external reuse at scale, executed sustainability commitments, and full population characterization, including comparison of TA1 derivation cohorts with the broader population.

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METRICS

End goal set by the program, intermediate metrics set by the performer

Required Metrics	Program-Level Targets
Nodes Live	Minimum 10 nodes live with data flowing and cross-node query enabled and at least two of those nodes onboarded using published procedures alone. The final network shall span at least four distinct data types, of which at least two are not electronic health record or claims sources.
Harmonization	>95% of committed sources mapped to the common model and passing quality checks by the end of the program
Service Delivery	On-time delivery of stratification, cohorts, and endpoint extracts delivered to TA3 and TA4 against dates agreed upon by the program; target of 95% on-time, zero missed dependencies that block a TA3 trial opening.
Privacy	Zero instances of successful reidentification under adversarial red-team testing by an independent team, repeated yearly at a minimum and after each major architecture change
Query Performance	≤5 seconds multisite query across 10+ node sites
Reuse	Five external research groups executing analyses against the SPECTRA platform by the end of the program
“Performer-Defined” Metric	Performers may include additional quantitative criteria for assessing progress across all phases and should align with TA2 goals and deliverables.

How targets are set:

Although the program sets the end state, the performer proposes the intermediate metrics to be assessed at G1 and G2 to facilitate tracking of technical progress.

TA2 metrics will be assessed at:

- **G1**: Month 10
- **G2**: Month 22
- **Final Evaluation**: Month 46

G=Gate

Note: Proposers must define their own G1/G2 intermediate metrics.

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CO-DEVELOPMENT

TA2 is the enabling layer for all SPECTRA TAs

To: TA1

Provides an analytic environment, harmonized cohort measures, population-scale comparison data, and the written assessment of how TA1 derivation cohorts differ from the broader population.

To: TA3

Provides trial-ready stratification, participant identification against eligibility criteria, endpoint data drawn from routine care, and characterization of the trial population's representativeness.

To: TA4

Provides a federated learning substrate, telemetry ingestion in the common schema, and a versioned model registry.

From TA1: Provides TA2 with candidate trajectory definitions and interaction specifications for population-scale testing and representativeness assessment.

From TA3: Provides TA2 with endpoint and eligibility requirements, and trial outcome data returned to the common data model.

From TA4: Provides TA2 with consented telemetry in the common data model, and model state for the versioned registry.

SPECTRA's Program-Wide Data Coordination Function: Provides alignment support for performer-generated data. Where TA2 and that function differ on a standard, the PM decides.

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Out-of-Scope

- **Centralized Repositories**: Centralized repositories requiring custodians to relinquish data custody
- **Data Re-Aggregation**: Re-aggregation/purchase of datasets already assembled by other federal programs.
- **Causal or Mechanistic Trajectory Modeling**: Any modeling on deeply phenotyped individuals is within the scope of TA1.
- **Supervised Learning**: Submissions relying solely on standard supervised learning are not sufficiently innovative for the purpose of this program.
- **Restricted-Access Analytic Environments**: Performer-only analytic environments do not meet the goals of TA2. Analytic environments should be accessible beyond just the performer that built them.
- **Networks limited to Electronic Health Record(EHR)/Claims Data**: EHR/claims data alone is not sufficient to meet the goals of TA2. Datasets should include new data types that may provide insight into trajectories (such as records of exposures, multiomics).
- **Preclinical Data**: Data generated from animal models or other preclinical laboratory studies without a path to linkage in human populations is out-of-scope.
  - *Note: This exclusion does not apply to nonclinical human data sources, including environmental exposure, education, behavioral, sensor, and multiomics data, which are expressly in scope.*
- **Foreign Nodes**: Proposals with **only** foreign nodes, or with datasets that do not include U.S.-based datasets, are nonresponsive.

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SUBMISSION PROCESS

Questions and how to propose

PROPOSING TO SPECTRA

- Proposers may submit to one or more technical areas. Submissions addressing a single technical area are welcome and expected.
- To respond to more than one TA, submit separate submissions when the submission portals open. Each must stand on its own should only one be funded and may note synergies if they exist.
- **TA2 Solution Summaries are due Dec. 2, 2026, at 3 p.m. ET.*** Follow the solicitation and Attachment A for the required format.

*Deadlines subject to change. Please reference the solicitation documents for the most up-to-date information.

Questions and updates

- Submit questions at solutions.arpa-h.gov/Ask-A-Question and select SPECTRA. General questions and answers are posted publicly.
- Email the program at SPECTRA@arpa-h.gov.
- Monitor SAM.gov for amendments and the posting of each Technical Area's Attachment A and B.

These informational materials are updated as of Nov. 16, 2026. Please reference the SPECTRA solicitation documents for the most up-to-date information.

Planning to propose to both TA1 and TA2?

- **Separate Solution Summaries**: Groups may propose to both TAs, but these solution summaries must be submitted separately to each respective TA.
- **Combined TA1 & TA2 Submissions *will not be accepted***.
- **Each submission must be workable independently**: Submissions to TA1 and TA2 from the same group are permitted but these submissions must be independently feasible.
- **Submissions may synergize**: If submitting for both TAs, groups may briefly reference synergies offered between the two independent submissions.
- **Overlaps in scope will be negotiated**: Overlapping costs and efforts between TA1 and TA2 submissions from the same group may be separated/reduced/eliminated during contract negotiation.

Reminder: Proposers must apply to TA1 and TA2 **SEPARATELY**.

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Planning to propose to both TA1 and TA2?

To prepare a responsive submission, note the key technical differences between TAs 1 and 2. Proposers should refer to the SPECTRA ISO for additional details.

Category	TA1: Analyze	TA2: Integrate
Scope	Produces ***individual-level*** patient trajectories and modeling to: 1. Identify gaps in biological understanding for hypothesis testing. 2. Discover causal connections.	Establish a federated network and common data model, identify gaps in large datasets, and analyze ***population*** characteristics such as incidence, prevalence, subgrouping, etc.
Core method	Causal/nonlinear interaction modeling based on SPECTRA data returns	Data federation and harmonization, privacy architecture, sustainability planning
Interface with SPECTRA TAs	Provides TA2 with testable trajectory definitions and hypotheses for population-scale analyses and enables patient stratification for TA3	Provides TA1 and TA3 with the analytic environment, harmonized cohort measures, and population-level analyses of how TA1 results differ from the broader population
Does NOT do	Build data infrastructure/standards or conduct *population-level* analyses	Conduct *individual* causal/mechanistic modeling

Note: Teams may submit to both TAs, but each submission must stand alone and be independently fundable. Submissions may note synergies, but neither submission may depend on or be a prerequisite for the other.

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Business, Acquisitions, and ISO

ARPA-H-SOL-26-163 Overview

Caitlin Burns
Agreements Officer, ARPA-H

These informational materials are updated as of Nov. 16, 2026. Please reference the SPECTRA solicitation documents for the most up-to-date information.

SPECTRA ISO Summary

- Solution Summaries are mandatory.
- Proposers who submit a Solution Summary may submit a full proposal regardless of encourage/discourage.
- No funding limits (or range) for individual projects.
- All awards will be Other Transactions (OTs).
- Resource sharing is encouraged.

Read the ISO!

These informational materials are updated as of Nov. 16, 2026. Please reference the SPECTRA solicitation documents for the most up-to-date information.

Solution Summaries

- Solution Summaries are **mandatory**.
  - TA1 and TA2 Solution Summaries due Dec. 2, 2026, at 3 p.m. ET*

- Use of Attachment A is mandatory.

*Deadlines subject to change. Please reference the solicitation documents for the most up-to-date information.

4.3 Solution Summaries (Pre-Proposal Submissions)

ARPA-H requires submission of a Solution Summary prior to submission of a Proposal for all Technical Areas. Solution Summaries allow ARPA-H to assess the viability of proposed concepts prior to Proposals.

Solution Summary Format (Attachment A)

Use of Attachment A — Solution Summary Format is required. All solution summaries submitted in response to this ISO must comply with the content, page, and formatting requirements outlined in Attachment A. Potential proposers are required to use the template provided. Information not explicitly requested in this ISO may not be reviewed.

These informational materials are updated as of Nov. 16, 2026. Please reference the SPECTRA solicitation documents for the most up-to-date information.

Eligibility Information

- **Government entities (agencies, Federally Funded Research and Development Centers, etc.) are not eligible.**
- **Non-U.S. entities are eligible.**
- **SAM.gov registration required for award.**
- **Awards, at any level, cannot be made to entities that are suspended or debarred, including key personnel.**

ARPA-H is primarily interested in proposals from commercial performers, academic institutions, and nonprofit organizations. **Federally Funded Research and Development Centers (FFRDCs) and government entities, including federal employees, are not permitted to respond to this ISO as a prime or sub-performer.**

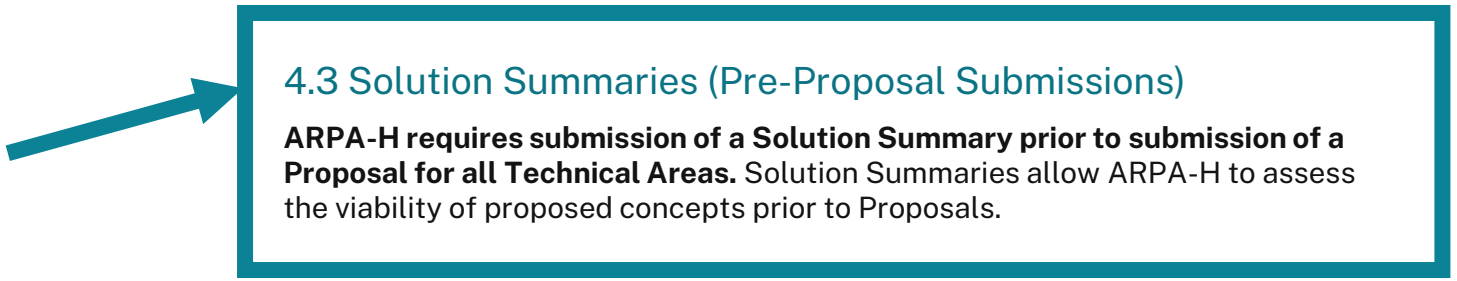
ARPA-H must prioritize awards to entities that will conduct funded work in the United States. Nondomestic performers are encouraged to collaborate with a domestic entity. ARPA-H will not make awards to entities organized under the laws of a covered foreign country per 42 U.S.C. 290c(n)(1)(D).

An active SAM.gov registration and Unique Entity Identifier (UEI) are required to receive an award. NOTE: SAM actions may take more than 14 business days to process; at times it may take up to 90 days. SAM is independent of ARPA-H and thus ARPA-H representatives have no influence over processing timeframes.

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Review Process

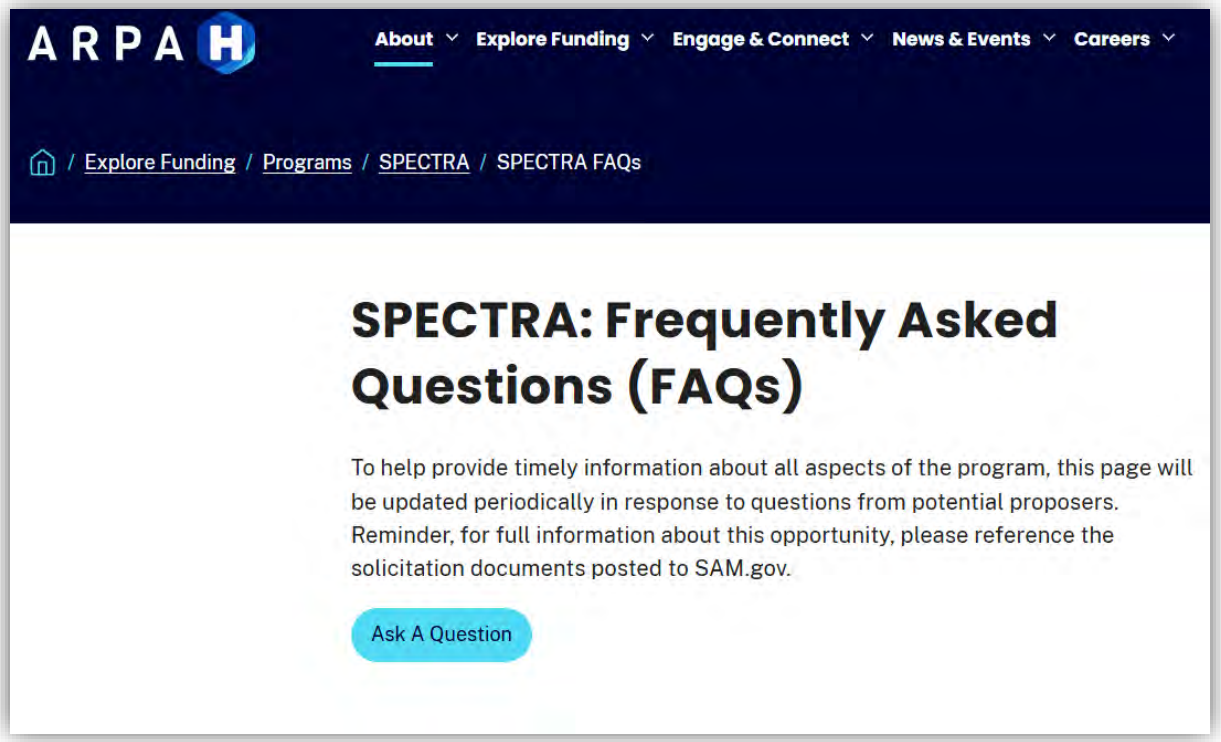
- **Solution Summaries are mandatory.**
- **Solution Summaries will be reviewed based on ARPA-H processes.**
- **Notification of Encourage or Discourage will be sent via email.**



These informational materials are updated as of Nov. 16, 2026. Please reference the SPECTRA solicitation documents for the most up-to-date information.

Questions and Answers

- Please check posted answers before submitting a question
- Submit via the Solutions site Ask-A-Question (select SPECTRA in the dropdown)
- The Solutions site can be found at: solutions.arpa-h.gov/ask-a-question

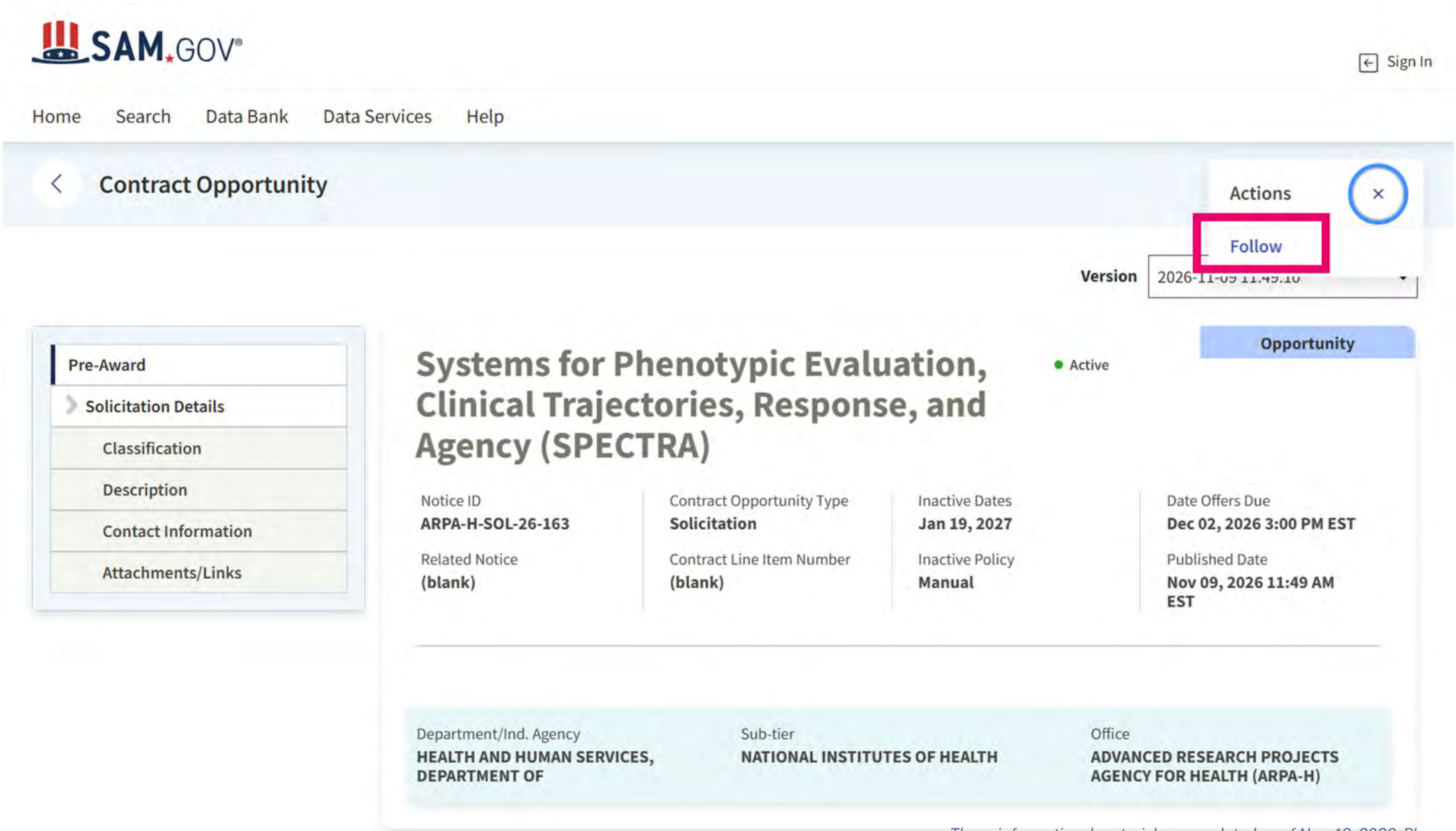


6.5 Questions and Answers

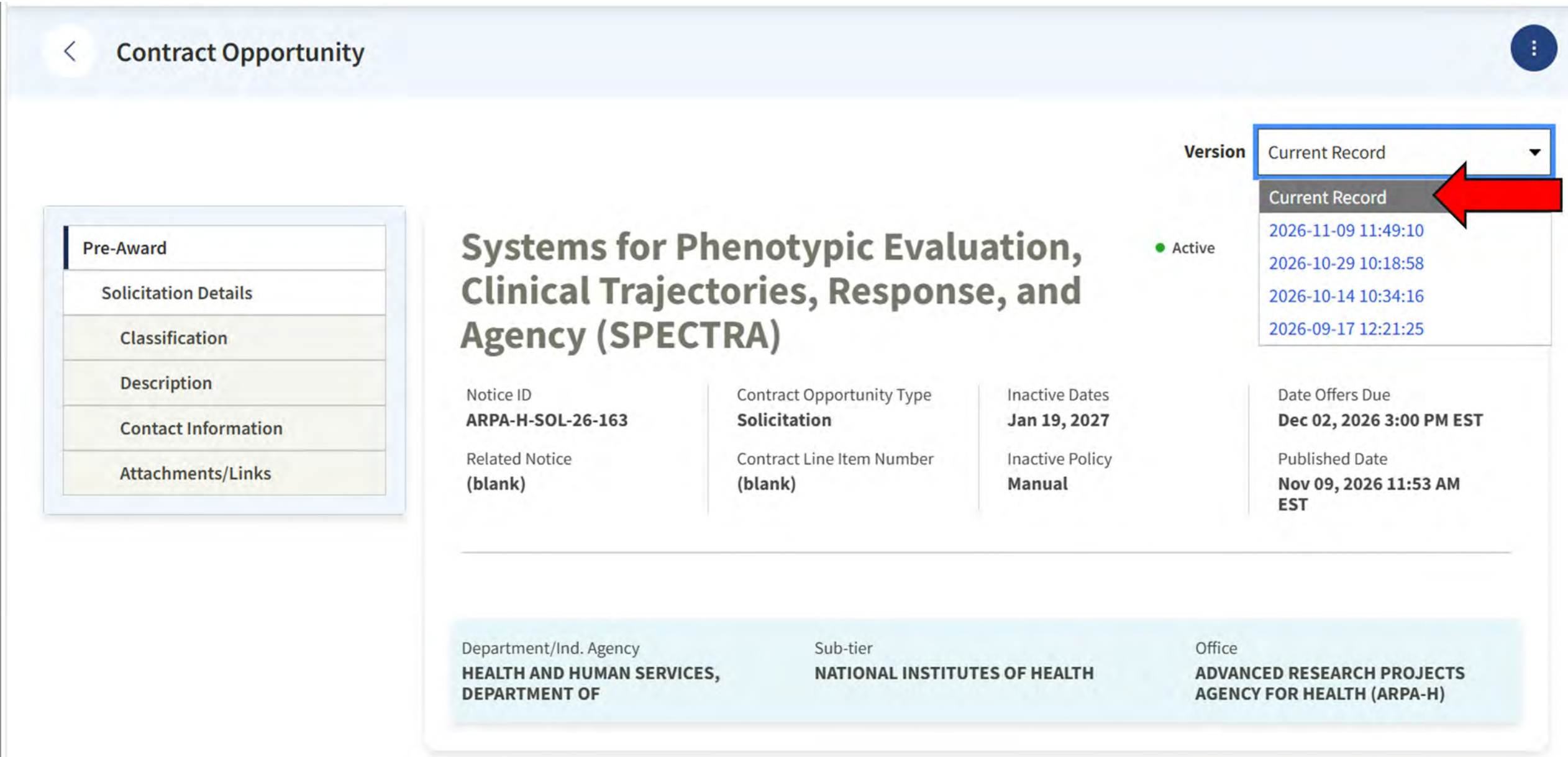
The following types of questions will not be answered:

- Which Technical Area a given team or concept should address
- Whether a specific idea or approach falls within SPECTRA's scope
- Preferred or recommended teaming arrangements
- Requests for ARPA-H's position on topics beyond the requirements of this solicitation

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Award Type — Other Transactions

OTs are agreements

- Mutual assent, expressed by a valid offer and acceptance; adequate consideration; capacity; and legality (i.e., these are contracts, but not Federal Acquisition Regulation (FAR) procurement contracts).
- Leverage commercial business practices more than traditional FAR procurements.

Collaborative

Increased collaboration and partnership, leading to more effective use of resources and knowledge sharing.

Flexible

- Many typical contract laws and regulations don't apply (e.g., Competition in Contracting Act, FAR, Cost Accounting Standards).
- Greater flexibility in project design and implementation.
- May fully negotiate data rights, patents, etc.

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Process and Checklist

Step 1: Solution Summaries Required

- Must use Attachment A
- Submit to: https://solutions.arpa-h.gov/submit-summary
  - TA1 and TA2 Solution Summary Deadline: Dec. 2, 2026, at 3 p.m. ET
  - Submission portal opens Nov. 18, 2026

Encouraged/ Discouraged

Step 2: Full Proposals

Details in upcoming ISO amendment

Selected/Not Selected

Step 3: Negotiation & Award

- Revised and/or additional documentation (as requested by ARPA-H)
- Real-time negotiations

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Final Guidance

- The final ISO is binding until/unless changes are posted as amendments to SAM.gov.
- Ask questions at https://solutions.arpa-h.gov/Ask-A-Question/ after checking the posted Frequently Asked Questions (FAQs).
- Register or update your registration in SAM.gov and the ARPA-H Solution Submission Portal as early as possible.
- **Read the ISO**.

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ARPA H