# Research Opportunity Announcement (ROA): OTA-25-003 Validation and Qualification Network (VQN) Public-Private Partnerships for Adoption and Implementation of New Approach Methodologies (NAMs)

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| **Participating Organization (s)** | National Institutes of Health |
| **Components of Participating Organizations** | This Other Transaction (OT) Research Opportunity Announcement (ROA) is to support the *Validation and Qualification Network (VQN) for Adoption and Implementation of New Approach Methodologies (NAMs)*. This research opportunity will be administered by the NIH Division of Program Coordination, Planning, and Strategic Initiatives (DPSPCI) Office of Strategic Coordination (OSC), also known as the Common Fund. |
| **ROA Title** | Validation and Qualification Network (VQN) Public-Private Partnerships for Adoption and Implementation of New Approach Methodologies (NAMs) |
| **Activity Code** | OT2: Application for an Other Transaction Agreement |
| **Research Opportunity Number** | OTA-25-003 |
| **Application Due Date** | Phase I: January 17, 2025<br><br>Phase II: by August 15, 2026<br><br>Phase III: by August 15, 2031 |
| **Earliest Start Date** | Phase I: Feb 1, 2025<br><br>Phase II: November 15, 2026<br><br>Phase III: October 15, 2031 |
| **Funding Instrument** | Other Transaction: An assistance mechanism that is not a grant, contract, or cooperative agreement. The Complement-ARIE Program is part of the NIH Common Fund. The OT awards are governed by 42 U.S. Code § 282 (n)(1)(b). |

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| **Funds Available and Anticipated Number of Awards** | Phase I: The Office of Strategic Coordination (OSC), also known as the Common Fund, intends to fund one (1) sole source award for the Design Phase.<br><br>Phase II: Expected duration of project period and future year funding will be provided contingent upon continued program success and the availability of appropriated funds. Award and total funding may increase or decrease over time based on programmatic needs, availability of funds, and awardee performance.<br><br>Phase III: Expected duration of project period and future year funding is contingent upon continued program success and the availability of appropriated funds. Award and total funding may increase or decrease over time based on programmatic needs, availability of funds, and awardee performance. |
| **Award Budget and Project Period** | Phase I: 12 months<br><br>Phase II: TBD, FY26–FY30<br><br>Phase III: TBD, FY31–FY35 |

## Purpose

The purpose of this Research Opportunity Announcement (ROA) is to support the development and implementation of a new Validation and Qualification Network (VQN) for adoption and implementation of New Approach Methodologies (NAMs), including a Design Phase to address specific program gaps and Funding Priorities for the subsequent Implementation Phases of the VQN Initiative, a component of the Complement-ARIE Program. This ROA facilitates submission of applications through eRA ASSIST that aim to catalyze the development, standardization, validation, and adoption of human-based new approach methodologies (NAMs) that will transform the way we do basic, translational, and clinical sciences.

In the initial **Design Phase**, a sole source Other Transaction (OT) Award will support planning stages for the development of a Public-Private Partnership. The NIH seeks input from the Foundation for the National Institutes of Health (FNIH) — and in alignment with the executed Request for Collaboration — to develop partnerships that enable new, impactful and timely synergies with other relevant stakeholders as part of establishing common data elements and standardized reporting, applying validation/qualification frameworks, and accelerating deployment and regulatory implementation of New Approach Methodologies (NAMs).

VQN priorities for the **Implementation Phase** will be developed and updated by the NIH COMPLEMENT-ARIE program staff or leadership based on evolving program needs and as informed by the Design Phase. Priorities will be determined by program/center/research needs in collaboration with input from program-funded investigators, other field experts, broader stakeholders, and Subject Matter Experts.

### Issue/gap being addressed:

There is an urgent need to accelerate the validation and adoption of NAMs for biomedical, pre-clinical, and regulatory uses and to streamline the regulatory frameworks for NAMs implementation and adoption. This demands that a framework is established comprised from all sectors that have skills and resources to work together in innovative and collaborative ways to meet this urgent need. Accordingly, the NIH Common Fund, along with its partner NIH Institutes, Centers, and Offices, seeks to develop a Public Private Partnership (PPP) among agencies, regulators, and public health officials at all levels of government, life sciences companies, non-governmental organizations, and academic biomedical research institutions to catalyze the development, standardization, validation and use of human-based new approach methodologies (NAMs) that will transform the way we do basic, translational, and clinical sciences.

## Background and Overview

New Approach Methodologies (NAMs) hold tremendous promise in understanding various biological processes leading to better assessment of disease risk and progression, and development of precision interventions in the context of personalized medicine. The recent passage into law of the FDA Modernization Act 2.0 reinforces drug registration without the requirement for the use of animals in safety toxicology assessment where alternative risk assessment tools are available. Similarly, the Toxic Substances Control Act (TSCA) as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, directs EPA to promote the development and timely incorporation of alternative test methods or strategies that do not require new vertebrate animal testing. While traditional animal models continue to be vital to advancing scientific knowledge, human-based NAMs offer unique strengths that, when utilized strategically or in combination, can complement animal models in ways that enable researchers to answer previously difficult or unanswerable questions, especially in areas where in vivo models are lacking or have consistently underperformed.

NAMs can be defined as any in vitro, in chemico, or in silico method that enables improved disease models. NAMs have proven to be valuable tools in basic, clinical, and toxicology research, and have been used to study the efficacy and toxicity of novel therapeutics. In chemico cell-free platforms use cell-free systems to study the interaction of drugs, toxicants, and other biological molecules. This method requires a prior knowledge about the interaction of the test agent with a biological substance, such as in skin-sensitization assessments. In vitro NAM models are systems that are performed generally outside of living organisms, including various types of mixed-cell type culture systems, organoids, and tissue culture techniques, such as microphysiological systems (MPS). In silico computational models incorporate biological data with mathematical and computer-based representations to construct models of human biology using methods such as data analyses, data mining, homology models, machine learning, pharmacophores, quantitative structure-activity relationships, and network analysis tools.

The overarching goal of the Complement-ARIE Program is to catalyze the development, standardization, validation, and use of human-based NAMs that will transform the way basic, translational, and clinical sciences are done. Specific program goals include:

- Develop better models and understand human health and disease outcomes across diverse populations.
- Develop NAMs that provide insight into specific biological processes or disease states.

- Validate mature NAMs to support standardization and clinical use.
- Complement traditional models and make biomedical research more efficient and effective.

Complement-ARIE will address current challenges in NAMs which include, validation and testing in complex systems, and the ability to generate preclinical data needed for first-in-human trials; characterize long-term, systemic and developmental health effects of environmental and drug exposures, and develop systems that better model the physiology and disease pathology of human diseases or conditions for which current experimental models are lacking (e.g. neuroscience and behavior research). Key focal areas of the NIH Common Fund investment include, but are not limited to:

- **Complex in vitro models** that emulate human organ structure, function, and response to study both normal physiology and disease pathology.
- **In silico multi-scale systems** simulating and modeling healthy/diseased individuals through computational approaches.
- **In chemico cell-free systems** that capture dynamic changes to assess chemical toxicity, chemical hazard and risk assessment, and inform adverse outcome pathways.
- **Integrated findable, accessible, interoperable, and reusable (FAIR) datasets and artificial intelligence (AI)-engines** to generate testable predictions (i.e., patient digital twins).
- **Combinatorial approaches** that combine two or more of the above approaches.

To achieve its goals, Complement-ARIE consists of the following key components:

- **Comprehensive NAMs Technology Development Centers (TDCs)** — stimulate the development of NAMs to address areas of greatest need, with emphasis on increased biological complexity and throughput, innovative combinatorial approaches, and data sharing.

- **NAMs Data Hub and Coordinating Center (NDHCC)** — provide overarching support for the Complement-ARIE Consortium and create integrated data structures, including standards for model credibility, improve FAIRness of NAMs-relevant data, and create a searchable NAMs repository.

- **Validation and Qualification Network (VQN)** — establish common data elements and standardized reporting, apply validation/qualification frameworks, accelerate deployment and regulatory implementation of NAMs.

Within each of the three key program components, training and outreach activities are required to facilitate dissemination, capacity building, and adoption of NAMs. Complement-ARIE will participate in strategic engagement with key partners from other federal agencies including regulatory bodies, industry, non-profits, and other NGOs to advance emerging opportunities in the development and use of NAMs in basic, translational, and clinical research.

Complement-ARIE will play a pivotal role in advancing NAMs and our current understanding of human health and etiology of human disease. This program will have near-term application in

fields such as mechanism elucidation, personalized precision medicine, safety pharmacology, predictive toxicology, and efficacy evaluation of candidate therapeutics.

## The Complement-ARIE Consortium

The VQN will participate in the Complement-ARIE Consortium whose purpose is to effectively guide all funded projects to meet the overall goals of the Complement-ARIE program. The consortium is composed of NIH staff from the trans-NIH Complement-ARIE Working Group and all award recipients from all phases of this Research Opportunity Announcement (ROA), the TDCs, and the NDHCC, and the VQN. The Consortium is led by the Complement-ARIE Steering Committee (SC). The SC will include a representative Program Director/Principal Investigator (PD/PI) from each awarded TDC, VQN, NDHCC, and an NIH Project Scientist. Members of the SC will elect the SC co-chairs from among the Complement-ARIE PDs/PIs. The SC Steering Committee (SC) Co-chairs, who will preside at all SC meetings and provide scientific leadership for the Consortium with significant input from NIH staff.

Award recipients agree to governance, through voting and decision making of the consortium through the SC. It is expected that most of the decisions on the activities of the SC will be reached by consensus. Other Consortium subcommittees may be formed as needed, and as deemed appropriate by the SC to further or achieve the goals of Complement-ARIE.

## Complement-ARIE Consortium Data Sharing

A central goal of the Complement-ARIE program is the harmonization of NAMs data collection, metadata, and the standardization of NAMs validation frameworks for wider NAMs adoption and use. NIH expects that all projects from all phases funded under this ROA will actively coordinate, collaborate, and share data with the NDHCC. The VQN will collaborate with the NDHCC to develop a framework for standards, metadata and common data elements (CDEs) that apply to all types of data generated to maximize potential for research, data integration, and NAMs benchmarking and evaluation for validation and qualification. The NDHCC and VQN will collectively create a mechanism to support data harmonization and will participate in trans-NIH efforts to support scientific collaboration and data sharing, partnership, and rapid dissemination of the NAMs produced by the Complement-ARIE program. The NDHCC and VQN will provide overall support and guidance to award recipients funded under this ROA in the following areas: (1) administrative operations and logistics, (2) data collection, curation, and integration, (3) data standardization, metadata development, ontology use, and CDE implementation, and (4) data management, sharing, search and use.

### VQN Initiative Phases

Although the description above pertains to the entire Complement-ARIE program and is included so potential applicants can consider formulation of their project with an overview of the entire program, THIS ANNOUNCEMENT APPLIES ONLY TO the Validation and Qualification Network (VQN) Partnerships for Adoption and Implementation of New Approach Methodologies (NAMs). The Validation and Qualification Network initiative will consist of three phases:

- Phase I — The **Design Phase (FY25)** will produce a white paper with a detailed plan to build and launch a PPP, focusing on the key primary processes of building the Validation and Qualification Network for adoption and implementation of new approach methodologies, with multiple stakeholders across academia, industry, NGOs,

government, and international groups, to develop and implement the Validation and Qualification Network, with the goal of creating the self-sustaining entity that will administer and manage the partnership in the public trust.

- Phase II — The **Implementation Phase I (FY26–FY30)** will be informed by the work products developed in the design phase to support the generation of data packages consistent with validation/qualification frameworks, based on common data elements and standardized reporting, as well as the dissemination of standards that are developed for the various categories of NAMs models to accelerate deployment and regulatory qualification and implementation of NAMs. This phase will also include the development of sustainability plans towards the creation of a self-sustaining entity that will administer and manage the partnership in the public trust. Execution of **Implementation Phase I** is dependent on program needs and availability of funds.

- Phase III — The **Implementation Phase II (FY31–35)** will be informed by the work products developed in Implementation Phase I to support the generation of data packages consistent validation/qualification frameworks, based on common data elements and standardized reporting, to accelerate deployment and regulatory qualification and implementation of NAMs. This phase will also include the implementation of a self-sustaining entity that will administer and manage the partnership in the public trust. Execution of **Implementation Phase II** is dependent on program needs and availability of funds.

## Proposal Format and Requirements:

**Phase 1 — The Design Phase (FY25):** The proposal should clearly and fully demonstrate the proposer's capabilities, knowledge, and experience and the budget proposed. The Project Plan should be limited to a maximum of 12 pages. Budget information and any related administrative documentation shall not count toward the total proposal page limit.

The applicant shall describe activities to be undertaken to develop the partnership, including but not limited to the following major milestones and associated tasks:

- Assemble a VQN Governance body, Scientific Steering committee to coordinate on determinations establishing criteria for selection of use cases, and to refine goals for the network based on stakeholders and biomedical research community needs for NAMs, including bioethical considerations.
- Plan development of a network with NIH, Industry, NGOs, CROs and fed partners, including ICCVAM.
- Identify primary "customers" and associated regulatory agencies (i.e. industries that will be using the NAM(s) in their research and development pipeline).
- Establish, convene, and manage a series of virtual meetings with at least four workstreams to identify industry/agency priority needs.
    1. ***Regulatory***: focused on issues related to navigating the current regulatory environment and how regulatory science and regulation can be optimized.
    2. ***Sustainability***: focused on developing models and approaches for how a successful PPP involving the support of NIH research programs at the outset can serve as a proof of concept to enable the development of a separate, long-term fiscally self-

sustaining entity. This may include dissemination of standards that are developed for the various categories of NAMs models, as well as issues related to overall commercial viability of new approach methodologies once marketed

3. ***Data Management and Integration***: focused on issues related to interactions and coordination with future VQN awardees and the NAMs Data Hub and Coordinating Center (NDHCC) to support the sharing and development of data standards including the support of interoperability with other NIH data ecosystems and non-NIH sources of NAMs relevant data.
4. ***Community Outreach and Training:*** focused on gathering perspectives from the broader stakeholder community (private and public sector) and opportunities to leverage training and outreach activities to facilitate dissemination, capacity building, and adoption of NAMs.

- Determine scope of validation and qualification efforts.
- Define pre-competitive data sharing capacity for stakeholders.
- Develop management plan for conflicts of interest and dispute resolution within the VQN and across other components.
- Identify complementary efforts such as ICCVAM Methods Developers Forum, international activities such as OECD GD34 updates (e.g., combinatorial NAM validation).
- Develop plans for selection of use cases of "late-stage" NAMs to address priority needs.
    - Establish minimum information and success criteria for identification of NAMs ready for validation and/or qualification. Criteria as well as reporting will require coordination with the "Data Management and Integration" workstream and should also consider the ICCVAM Validation Working Group report key concepts.
- Establish process for identification of key components for validation studies, including but not limited to:
    - Chemical procurement/QC/distribution,
    - Laboratory support for inter-lab studies
    - Develop validation management plans.
- Solicit, receive, manage, steward, and acknowledge donations from partner organizations.
- The applicant shall describe the deliverables and timeline relevant for the major tasks proposed in the application, including but not limited to:

**Months 1–6**

- In coordination with the NIH Office of Strategic Coordination, the VQN will establish a detailed plan for full execution of the PPP and describe intermediate milestones for the delivery of this plan to the NIH. The first 6 months will encompass defining the detailed scientific research plan and potential participant engagement. The FNIH will lead stakeholder working groups to conduct project planning, milestone-based proposal development, and development of a final research plan. Specific tasks include:
    - Convene a high-level executive stakeholder meeting to refine the plan for partnership (Month 0–3)
    - Convene 2 public workshops to acquire multidisciplinary community input on the design of the partnership (Month 3–6).

**Months 6–12**

- The FNIH will then take the next 6 months to engage all necessary partners who are willing to join the PPP and help facilitate the launch of the Implementation Phase I. These 6 months will also include the development of necessary agreements, such as research collaboration agreements CDAs, IP policies, and required contracts, as needed. Specific tasks include:
  - With input from NIH Staff and feedback from workshops, establish and support 3–6 stakeholder working groups. Organize one virtual 1 hour meeting each month for each working group to carry out specific tasks needed to develop the Implementation Phase (Month 6–12).
  - Prepare a detailed Implementation plan for the VQN with WG chairs (Month 6–12).
  - Assemble necessary partners and contractual agreements for the Implementation Phase (Month 6–12).

**Months 9–10**

- The NIH expects delivery of the detailed implementation plan by producing a White Paper by Month 9–10 or earlier. Describe a specific timeline and intermediate milestones for the delivery of the plan by this date. Details will be specified in the OT agreement.

**Phase II:** The project will transition to the Implementation Phase I based on successful completion of the Design Phase and subject to modification based upon programmatic needs and availability of funds. The Implementation Phase I will involve, but not be limited to, the following activities:

- Coordinate VQN activities with Industry, NGOs, CROs and federal partners.
- Select use cases (across NAMs categories)
- Support at least 8 use case validation and qualification studies
- Report biannually to both NIH and stakeholders at large
- Manage PPP interactions, as defined during the Design Phase, with regulators, industry, CROs in NAMs dev (e.g. via ICCVAM Method Developers Forum [MDF]) as part of the Consortium triumvirate which includes the Technology Development Centers, the NDHCC, and the VQN.
- Coordinate with ICCVAM WG and other entities, such as 3Rs Collaborative and HESI.
- Develop and apply reporting standards for NAMS in conjunction with the NDHCC and TDCs.
- Convene the VQN Scientific Steering Committee which will evaluate whether mature NAMs nominated by the Tech Dev Centers meet minimum standards for validation/qualification framework and are ready to formally enter the VQN pipeline.

- Identify training opportunities with PPP partner groups in conjunction with consortium training and community engagement activities.

- Coordinate w/ NICEATM to input validated NAMs in CAMERA (Collection of Alternative Methods for Regulatory Application that will be established by NICEATM).

- Engage with international stakeholders, such as OECD and other regulatory agencies, towards global harmonization in the regulatory use/acceptance of NAMs.

- Develop long term sustainability plans.

**Phase III**: The project will transition to Implementation Phase II based on successful completion of Implementation Phase I and subject to modification based upon programmatic needs and availability of funds. The Implementation Phase will involve, but not be limited to, the following activities:

- Coordinate with Industry, NGOs, CROs and federal partners. Make necessary adjustments to the structure and processes of VQN based on feedback from NIH and other stakeholders.

- Continue annual engagement of stakeholders and NAM developers to guide priority needs. Engage the stakeholders as to the possibility of sustaining the VQN beyond year Implementation Phase II.

**BUDGET**

**Phase I — The Design Phase (FY25):**

- Provide a detailed budget for all costs through the 12-month performance period (2/1/2025–1/31/2026) for each major milestone proposed in the application. See Application Content below for further guidance.
- Provide a budget justification to accompany the detailed budget which shall include an explanation of how FNIH will obtain the necessary expertise, effort, and resources to carry out the major tasks proposed in the application.

**Phase II:** Project Requirement and Award Modification Request Format details for the future phases of this ROA, Implementation Phase I, will be provided by NIH and phase transition subject to successful completion of the Design Phase, programmatic needs and availability of funds.

**Phase III:** Proposal Format and Requirement details for the future phases of this ROA, Implementation Phase II, will be provided by NIH and phase transition subject to successful completion of the Implementation Phase I, programmatic needs and availability of funds.

## Award Project Duration:

Phase I: The period of performance for this OT award will be a 12-month base period.

Phase II: TBD, FY26–FY30

Phase III: TBD, FY31–FY35

## Data Sharing Requirements

**Phase I:** No data sharing requirement applies to the **Design Phase**. It is not expected that this phase of the project will gather or develop data.

**Phases II–III**: For the future **Implementation Phases**, applicant(s) may be required to include a plan for data sharing and a collaboration plan up to one (1) page total, which should address data sharing requirements for the project. The Validation and Coordination Network (VQN) will coordinate with the NAMs Data Hub and Coordinating Center (NDHCC) and follow the NIH Data Management and Sharing Policy. If data sharing will be restricted in any way, applicant must state how and why, including the potential impact of this restricted sharing on the proposed project and Complement-ARIE as a whole.

## Eligibility Requirements

**Phase I:** The Foundation for the National Institutes of Health (FNIH) is the only eligible applicant for the Design Phase of this ROA.

**Phase II:** Transition to Phase II is contingent upon satisfactory performance during Phase I and subject to modification based upon programmatic needs and availability of funds.

**Phase III:** Transition to Phase III is contingent upon satisfactory performance during Phase II and subject to modification based upon programmatic needs and availability of funds.

## How to submit the application

**Phase I:** Application must be submitted through NIH's ASSIST (eRA Commons) site by **5:00 p.m. local time on January 17, 2025** at https://public.era.nih.gov/assist/public/login.era. Paper applications will not be accepted. Application must be submitted by an authorized organizational representative. Please, see "Resource only for Other Transaction Authority (OTA) Users of ASSIST" at the eRA Training ASSIST webpage.

**Phase II:** Submission details and due dates for the future phases of this ROA will be provided by NIH.

**Phase III:** Submission details and due dates for the future phases of this ROA will be provided by NIH.

## Application Content

**Phase I:** All pages should be Arial 11pt, single space with 1" margins. The following is a list of the required application components for Phase I Design Phase. Application details and due dates for the future phases of this ROA, Implementation Phase I and Phase II, will be provided by NIH.

## 1. Abstract

Provide a summary of the planned activities and approaches and key achievable goals (no more than 1 page).

## 2. Key Personnel

Include a CV or NIH biosketch (no more than 3 pages in length, limited to relevant expertise in the last 10 years), for each of the key personnel who have committed to participating in the project if it is awarded. In the context of this project, it is especially important to highlight expertise of personnel with NAMs (e.g. complex in vitro models, in silico modeling and simulations, in chemico cell-free systems, and/or integration of datasets addressing the FAIR principles and coupled with AI engines to generate testable predictions and risk assessments), as well as evidence of ability to build and manage complex, multi-entity public-private partnerships and to work collaboratively. Provide a table listing all personnel, including all to be named personnel, role on the project, and percent effort to be committed.

## 3. Project Plan (Tasks and Milestones)

This document should include a detailed description of the Design Phase activities and how these activities will be used to inform the Implementation Phase to establish the Validation and Qualification Network. Provide a summary of major tasks to be accomplished with milestones and benchmarks, a timeline, and deliverables. Provide a description of milestones for the proposed project period and associated costs in up to 3 pages.

## 4. Budget and Budget Justification

The Budget section must provide a realistic, fully justified annual budget and cost proposal for performing the work specified over a period of one year. The Applicant may complete the SF424 budget or use any budget format (i.e., spreadsheets) that details all required budget categories (see SF424) and should include a justification (narrative). Budget information and any related administrative documentation shall not count toward the total proposal page limit. The applicant should propose the total cost required for the Design Phase activities and indicate the proposed cost share contribution toward the total cost of the project as well as the proposed requested funds from NIH. The proposed NIH contribution **should not exceed $300,000.** The budget justification must be detailed, and it must provide explanation as to how the amounts requested were determined. The budget shall contain sufficient information to allow the Government to perform a basic analysis of the proposed cost of the work.

## 5. Other Support:

The Applicant shall provide a listing of all current and prior U.S. federal or state government funding (both direct and indirect) relevant to this research area. The Other Support instruction and required form, can be found at Other Support | Grants & Funding.

## 6. Cost Sharing

Cost Sharing is required. The applicant must propose a financial plan that includes non-federal resources. The budget submission must clearly identify and justify the use of these resources.

Any voluntary cost share must be supported in the application by including a letter of support from the providing organization(s)/individual(s).

**Phase II:** Application content for the future phases of this ROA will be provided by NIH.

**Phase III:** Application content for the future phases of this ROA will be provided by NIH.

## Objective review process

### All Phases:

Submissions will undergo an objective review process.

### Reviewer Selection:

Federal and non-federal experts with relevant expertise (e.g., management of extramural awards to spur biomedical R&D via public-private partnerships for Phase 1–Design Phase) will provide an objective review of the application/plans submitted in response to this ROA.

### Conflict of Interests:

Reviewers shall disclose any conflict of interests (COI) that might preclude their participation in the review process, as per NIH guidelines. Each NIH reviewer must certify, under penalty of perjury (US Code Title 18, Chapter 47, Section 1001), that to the best of the reviewer's knowledge all conflicts of interest with the applications or R&D contract proposals have been disclosed.

### Review Criteria:

**Phase I- The Design Phase (FY25):** NIH and other federal agency subject matter experts in the management of extramural awards to spur biomedical R&D via public private partnerships will weigh in on the qualifications and prior track record of the sole source with similar tasks, qualifications of the Team, likelihood of accomplishing the proposed work in the allotted time, appropriateness of the budget requested. Specific binary questions (Yes/No) are as follows:

1. Does the Applicant have proven track record of performing similar tasks/projects?
2. Are the qualifications of the Team appropriate to support the proposed work?
3. Are the proposed deliverables and milestones adequate to support the proposed work?
4. Is the indicated timeline appropriate for the proposed Scope of Work?
5. Is the requested budget breakdown appropriate for the proposed Scope of Work?
6. Is third-party subcontract work justified?
7. Overall Assessment: Recommend Do Not Recommend

Additionally, reviewers will be asked to provide comments including a brief summary supporting their recommendations. An OT award will be made if the recipient can sufficiently demonstrate

the organization's ability to build and manage a complex, multi-entity public-private partnership that seeks to consolidate a national ecosystem for the validation and qualification of New Approach Methodologies within 12 months and within budget.

**Phase II:** Review criteria for the future Implementation Phase I of this ROA will be provided by NIH.

**Phase III:** Review criteria for the future Implementation Phase II of this ROA will be provided by NIH.

Questions about this opportunity should be emailed to Complement-ARIE@od.nih.gov

## Agency Contacts

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| **Scientific/Research Contact** | Margaret Ochocinska, Ph.D.<br>Office of Strategic Coordination (OSC)<br>Division of Program Coordination, Planning, and Strategic Initiatives<br>Office of the Director (OD), NIH<br>Email: ochocinm@mail.nih.gov and Complement-ARIE@od.nih.gov |
| **Other Transactions Authority Agreement Contact** | Erna Petrich<br>Team Lead, Other Transactions Agreements Officer<br>Office of Strategic Coordination (OSC)<br>Division of Program Coordination, Planning, and Strategic Initiatives<br>Office of the Director (OD), NIH<br>Email: DOTM@mail.nih.gov (Subject line must include the words "Complement-ARIE") |