Complement-ARIE: Complement Animal Research In Experimentation

NAMs Reduction to Practice Challenge

**Q & A Panel Discussion** 



December 10, 2025 3PM EST

### Today's Agenda



- Opening Remarks
- Background
- Complement-ARIE Challenge
  - Overview
  - Timeline
  - Eligibility
  - Evaluation Criteria
  - Submission Process & Requirements
- Live Q&A Session



Please type questions you have throughout the webinar in the O&A box



Questions submitted via the Q&A box will be answered at the end of the presentation



Participants should remain muted



The webinar will be recorded and made publicly available



### Today's Panelists (Presenting)





Margaret Ochocinska, Ph.D.

Program Leader, The Common Fund, Office of Strategic Coordination (OSC)



Christine Happel, Ph.D.

Program Director, Office of Special Initiatives, National Center of Advancing Translational Sciences (NCATS)



Thad Schug, Ph.D.

Program Director, Population Health Branch, National Institute of Environmental Health Sciences (NIEHS)

### **Common Fund Historical Perspective**



2004: NIH Roadmap is launched

December 9, 2006: Congress unanimously reauthorizes the NIH



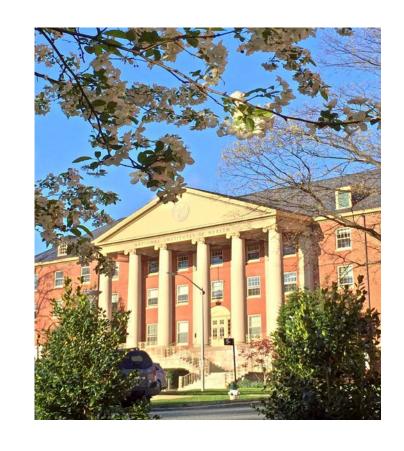
Establishes the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within Office of the Director and the NIH Common Fund to provide a dedicated source of funding to enable *cross*-NIH research

# The Common Fund Moves the NIH Mission Forward – Faster

Supports bold scientific programs that catalyze discovery across all biomedical and behavioral research

Advances areas of biomedical and behavioral research important to the missions of multiple NIH Institutes and Centers

Spurs subsequent biomedical advances that otherwise would not be possible without an initial strategic investment



# Features of Common Fund Programs and How They Catalyze Biomedical Discovery

Making substantial investments in time-limited, goal-driven programs that significantly change the trajectory of biomedical research.



Accelerate emerging science



Remove research roadblocks



Enhance the research workforce



Support high-risk, high-reward science

# Common Fund Science and Management are Collaborative



Scientists from various disciplines provide input as we plan new programs.



Researchers participate in interdisciplinary consortia to tackle shared goals.



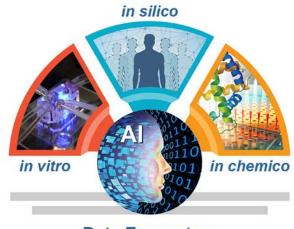
Leadership and staff from Institutes, Centers, and the Office of the Director work together to design funding opportunities and oversee the projects.

### **Complement-ARIE Program: Purpose and Goals**

<u>Purpose</u>: 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

#### Goals:

- 1. Better model and understand human health and disease outcomes across various populations.
- 2. Develop NAMs that **provide insight into specific biological processes** or disease states.
- 3. Validate mature NAMs to **support regulatory use** and standardization.
- 4. Complement traditional animal models and **make** biomedical research more efficient and effective.



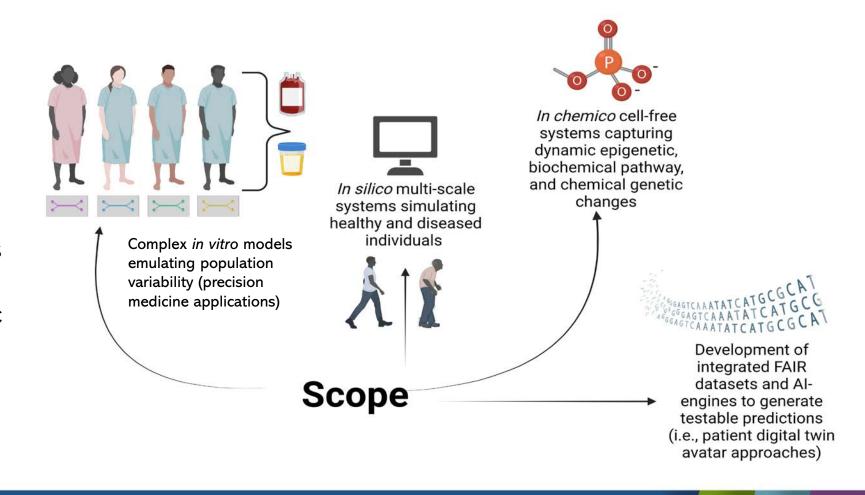
**Data Ecosystem** 

### Complement-ARIE Program: Major Work Products

### **Program Goals:**

### NAMs that incorporates the following features:

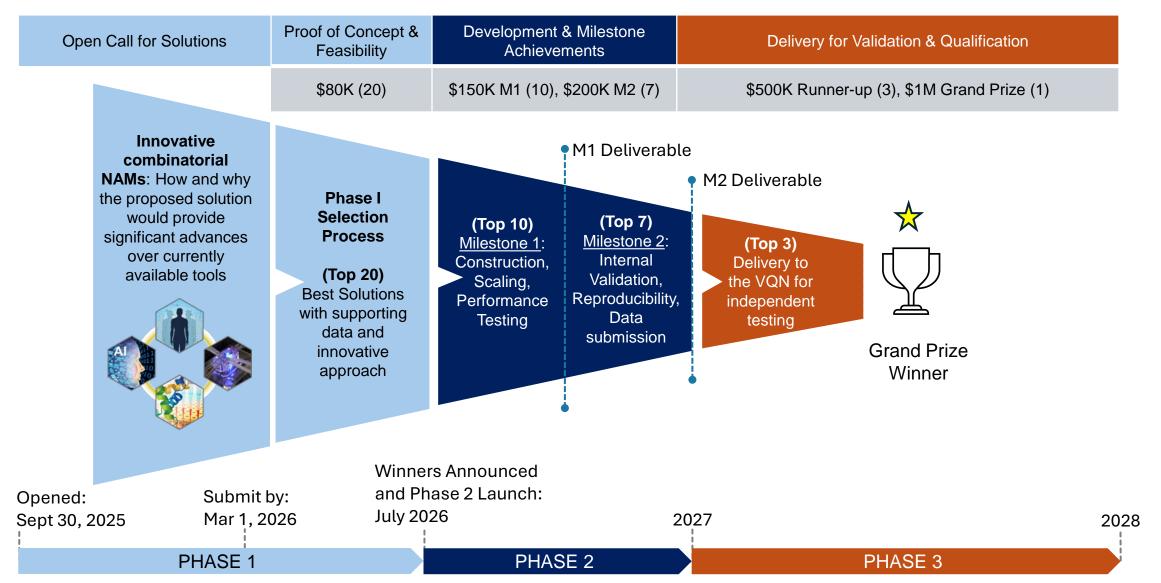
- Complex in vitro models emulating population variability
- In silico multi-scale systems simulating healthy/diseased individuals
- In chemico cell-free systems capturing dynamic changes
- Combinatorial NAMs and integrated FAIR datasets and AI-engines for all NAMs



## **Building the Future of NAMs – Reduction to Practice**

- The Reduction to Practice (RTP) Prize competition is a cutting-edge challenge to bring early stage combinatorial NAMs to a practicable and usable form within three years.
- \$7,000,000 in total prize money across 3 phases
- Phase 1 Submission period Sep 30, 2025 Mar 1, 2026;
  - Winners announced in July of 2026.

# Complement-ARIE NAMs Reduction to Practice (RTP) Challenge



### Complement-ARIE RTP Challenge – Priority Areas



#### **Chronicity**:

 Characterizing long-term, systemic, and developmental health effects of environmental and drug exposures, including chronic disease.

#### **Neurobiological Models:**

 Neurodegenerative and neurodevelopmental disease models, neuropsychiatry, ophthalmology, and/or modeling behavioral research.

#### **Personalized Medicine:**

 Human-specific models to address biological therapeutics, including monoclonal antibodies, human proteins, oligonucleotides, gene editing, and cell therapies and incorporating population variability and sex as a biological variable.

### Complement-ARIE RTP Challenge – Priority Areas



#### **Cross-Disease Pathogenesis:**

 Platforms that address developmental, metabolic, immune, inflammatory, reproductive, or nutritional health that span multiple diseases or are broadly generalizable across diseases including chronic disease.

#### **Toxicology and Safety**

• Strategies that replace conventional animal toxicology or safety pharmacology studies, including assessment of potencies associated with systemic toxicity via either mechanism- or tissue-based assays assessed via proxy by simpler high-throughput models.

#### **Human Health Protection**

 Strategies that inform special studies that are important for human health protection and include methods to assess development and reproductive toxicity (i.e. DART), neurotoxicity, endocrine disruption, immunotoxicity, and carcinogenicity

### Complement-ARIE RTP Challenge



#### What is a "Combinatorial NAM" Solution?

A combinatorial NAM is one that integrates NAM technology across modalities (in vitro, in chemico, in silico) OR two distinct NAM technologies within a modality. The idea is to create a cohesive solution that leverages multiple methodologies for a comprehensive insight into human biology.

#### How mature must a NAM be to be responsive to this challenge?

 NAM submissions should be at a sufficient technical readiness level to be ready for validation and/or qualification within a 3-year timeframe.

### Complement-ARIE RTP Challenge Timeline



Challenge Launched & Submission Portal Opened



Submission Deadline



9/30



3/1

July 2026



Informational Webinar



Winners
Announced
and Phase 2
launch (est.)

### Participant Eligibility

Carefully review the Eligibility and Participation Rules posted on

https://www.herox.com/Complement-ARIE-RTP





Identify a **Team Captain** who will submit on behalf of a group of individuals.

If the Team wins, the **Team Captain** will be paid the cash prize in full.

The **Team Captain** must be a U.S. citizen or permanent resident to be eligible to receive a cash prize\*.

\*Non-U.S. citizens and non-permanent residents are <u>not</u> eligible to win a monetary prize (in whole or in part). Their participation as part of a winning team, if applicable, may be recognized when the results are announced.



### **Entity**

Identify a **Point of Contact** who will submit on behalf of a legally established <u>organization</u>, <u>institution</u>, <u>or corporation</u>.

If the Entity wins, the **Entity** will be paid the cash prize directly.

The **Entity** must be incorporated in and maintain a primary place of business in the United States to be eligible to receive a cash prize.

### A Note About Using Federal Funds to Compete

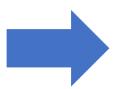


An Innovator may <u>not</u> use Federal funds from a grant award or cooperative agreement or other transaction (OT) awards to develop their Challenge submissions or to fund efforts in support of their Challenge submissions <u>unless</u> use of such funds is consistent with the purpose, terms, and conditions of the grant award or cooperative agreement.

#### IF

... you intend to use Federal funds, and

... the use of such funds is consistent with the purpose, terms and conditions of the award



#### **THEN**

... you must register for and participate in the Challenge as an **Entity** on behalf of the awardee institution or organization, <u>and</u>

... the prize must be treated as program income for purposes of the original grant or cooperative agreement in accordance with applicable Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR § 200)

### Proposal Evaluation Criteria





#### **Approach**

Clear project plan leading to validation and delivery of NAM solution that incorporates best practices in the field and integrates approaches; strategies for roadblocks; adequate metrics; likelihood for success in a proposed context-of-use



#### **Team**

Interdisciplinary expertise of the team or entity submitting the idea, end-user engagement



# Feasibility and Approach

Proposed combinatorial NAM can advance to validation within the duration of this challenge, address a proposed context-ofuse, backed by substantive preliminary data



#### **Innovation**

Novelty and innovation of the proposed idea.



### Potential Impact

Value of Combinatorial NAM approach, addressing area of critical need, 3Rs, resolving roadblock to development/validation

### Submission Process



- 1. All **Team** or **Entity** members must carefully review the complete Challenge Announcement posted on <a href="https://www.herox.com/Complement-ARIE-RTP">https://www.herox.com/Complement-ARIE-RTP</a>
- 2.The **Team Captain** or **Entity Point of Contact** must create an account, click on "*Solve this Challenge*". The guidelines and rules will be under "Summary" and in the "Resources" section.



3. Provide all requested information and submit an entry in the portal no later than 11:59 PM Eastern Time on March 1, 2026

#### **Submission Requirements**

- Cover page: Submission Title, Team/Entity name and location, logo (optional)
- Executive Summary and plan language summary
- √ Team composition and interdisciplinary expertise
- ✓ Project Description and Data:
  - ✓ Priority areas or defined need of NAM
  - ✓ Combinatorial NAM integration
  - Novelty of the idea
  - Technical specifications
  - Approach planned activities, milestones, and technical readiness on a feasible timescale
  - Data to support readiness of the technology
  - ✓ Scientific rationale



### Questions

Follow up questions can be emailed to: <a href="mailto:gethelp@herox.com">gethelp@herox.com</a>

Additional information about Complement-ARIE can be found at <a href="https://commonfund.nih.gov/complementarie">https://commonfund.nih.gov/complementarie</a>