

Complement-ARIE: Complement Animal Research in Experimentation

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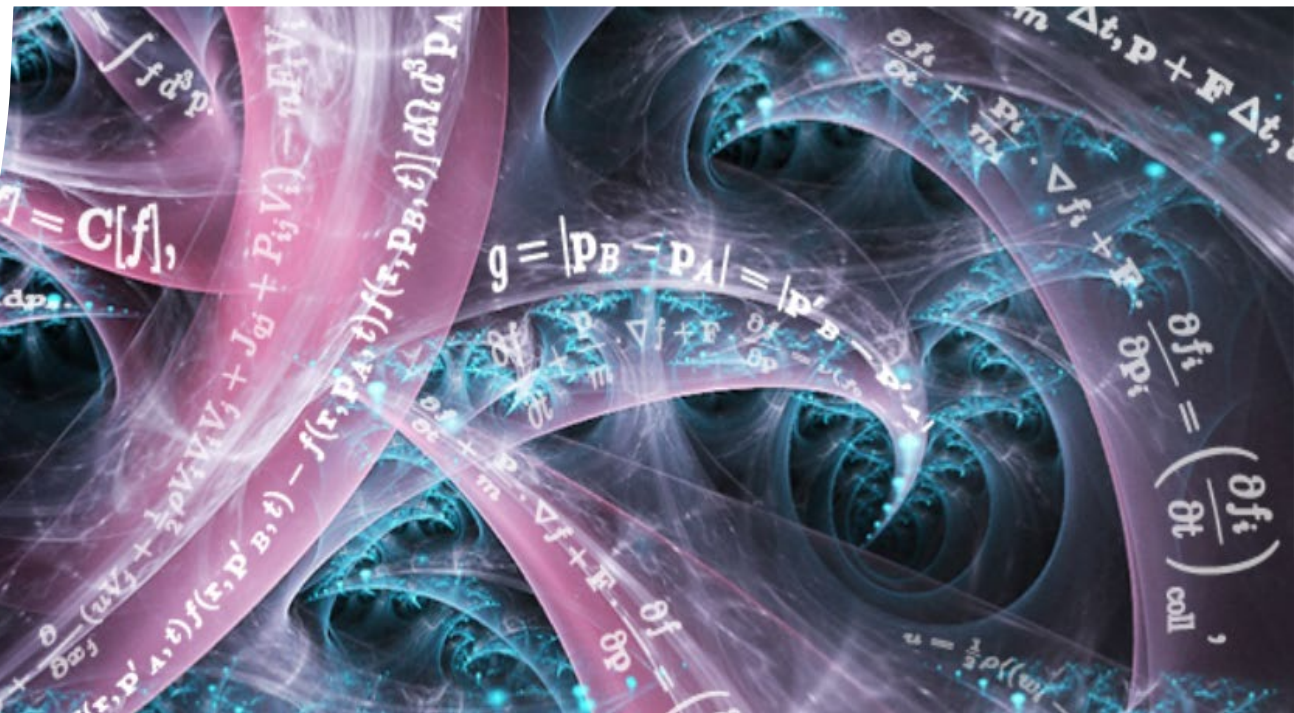
Program Leader
Re-engineering the Research Enterprise
Office of Strategic Coordination, NIH, OD

ICCVAM Public Forum

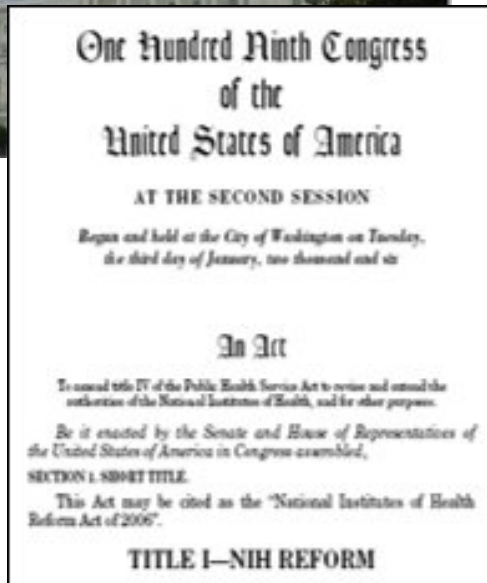
July 29, 2026



National Institutes of Health
Office of Strategic Coordination–The Common Fund



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 *trans*-NIH research

The Common Fund Moves the NIH Mission Forward – Faster

Supporting 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

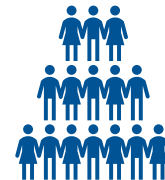
Making substantial investments in time-limited, goal-driven programs that significantly change the trajectory of biomedical research.



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 diverse disciplines provide input as we plan new programs.



Researchers participate in interdisciplinary consortia to tackle shared goals.

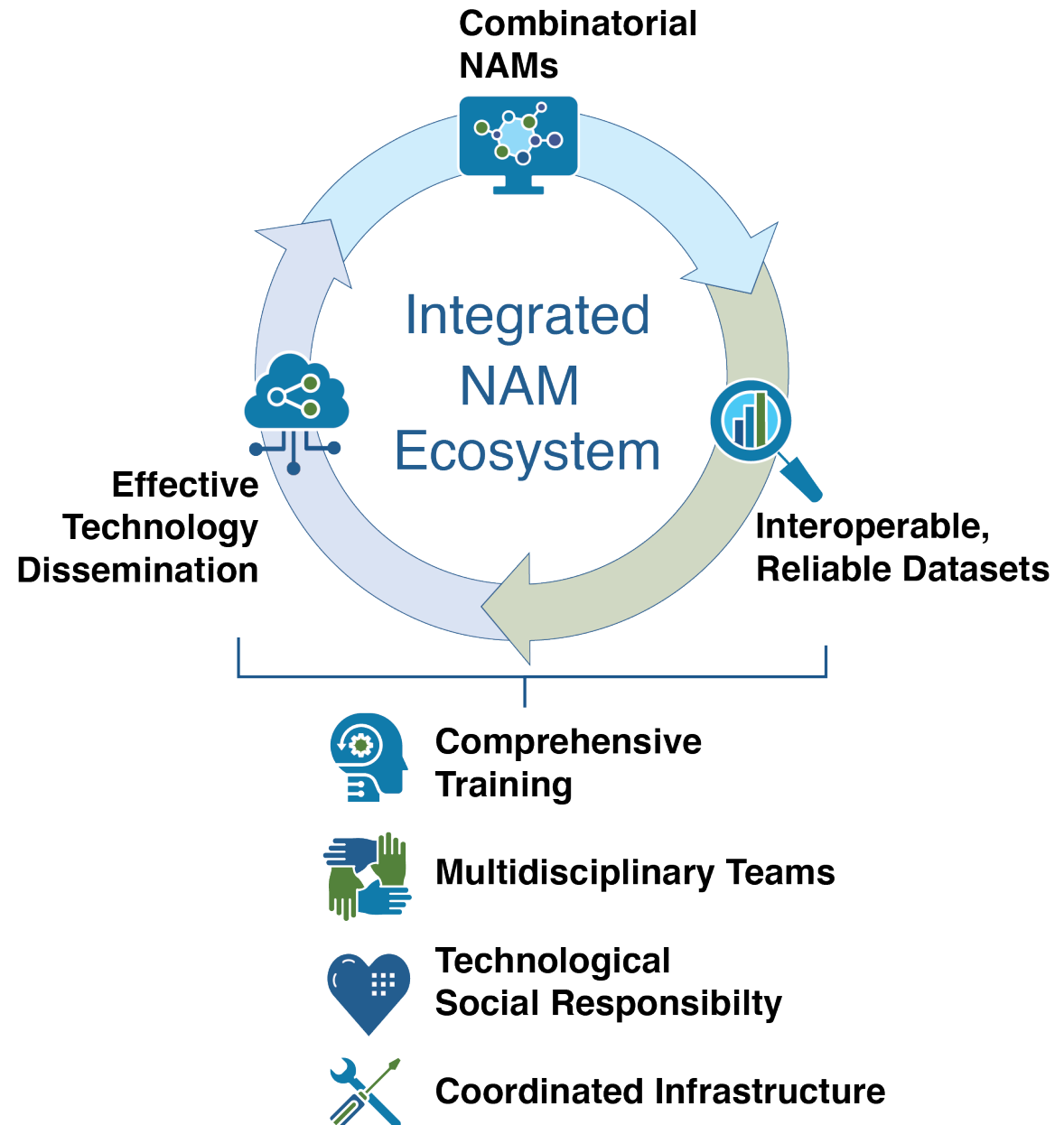


Leadership and staff from Institutes, Centers, and the Office of the Director work together to design funding opportunities and oversee the projects.

NIH VISION OF NAMs

**An integrated
ecosystem to
catalyze scientific
discovery**

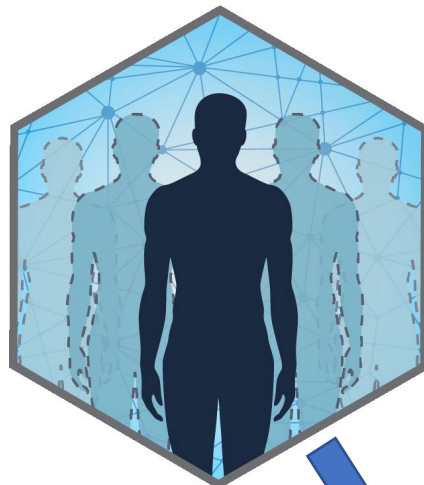
*NIH Advisory Committee
to the Director, December
2023*



Build on NAMs activities across NIH

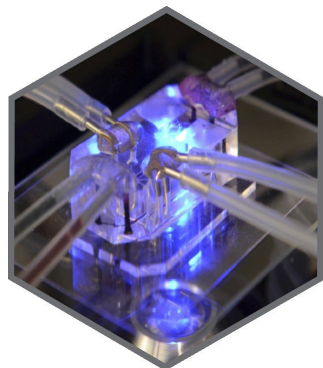
Digital Twin Models

Digital Twins for treatment of cancers and neuropsychiatric diseases, host-gut microbiome studies



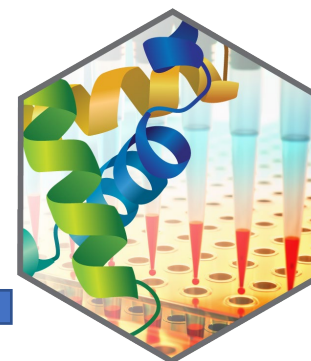
In Silico Models

In silico and AI/ML models for neurodegenerative disease, wound healing, learning/behavior, infectious disease propagation, many other diseases



Complex In Vitro Systems

MPS and 3D organoid models for multiple tissues, organs and disease conditions



In Chemico Screening

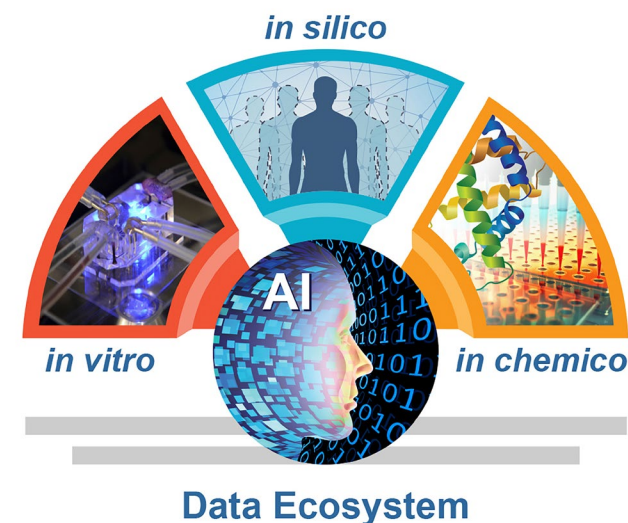
Tox21 high-throughput studies, biochemical assays for skin irritation, ocular toxicity

Statement of Purpose and Goals of Complement-ARIE

Purpose: 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 representative of the patient 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 models and **make biomedical research more efficient and effective.**



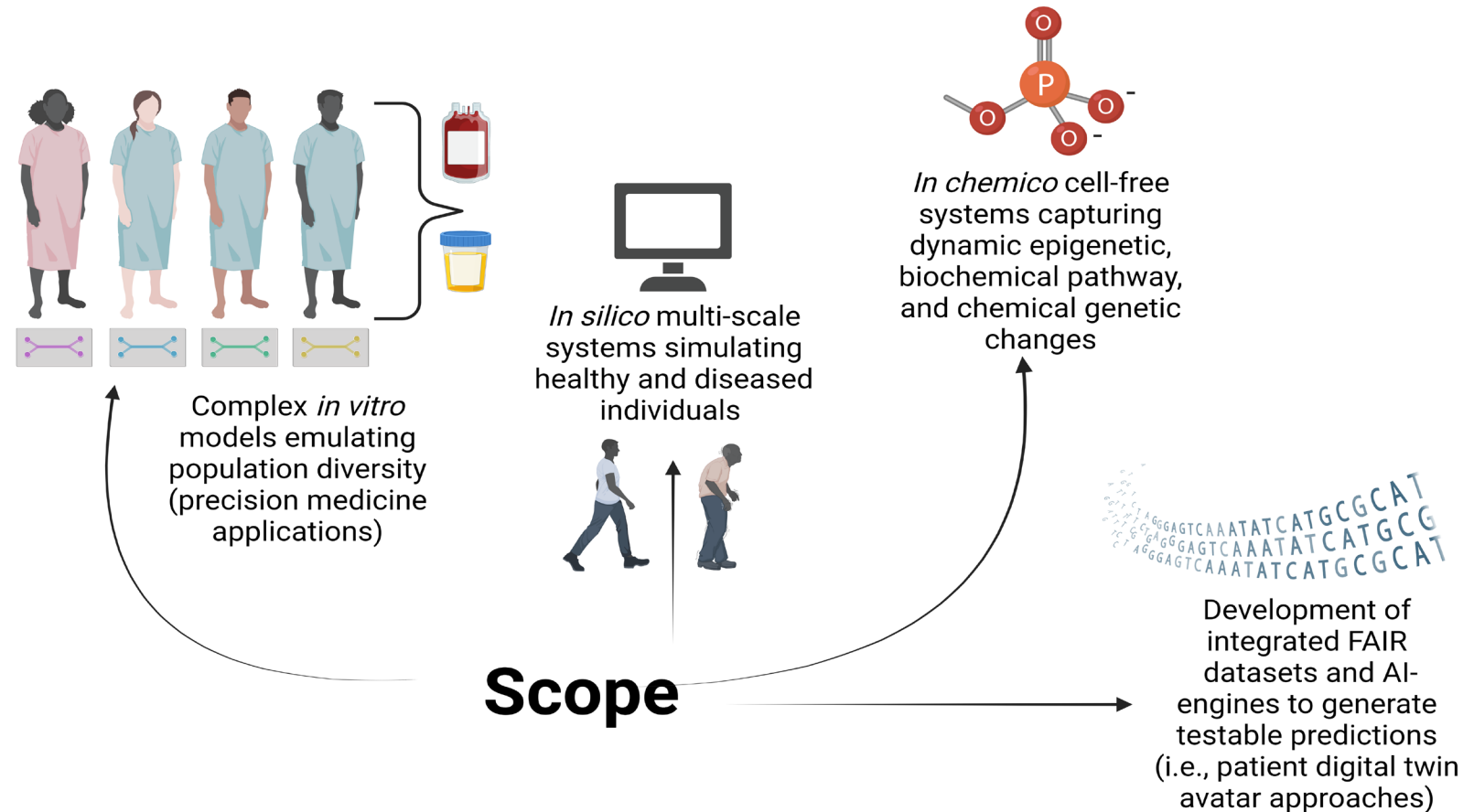
Link to Complement-ARIE website

Complement-ARIE Program: Major Work Products

Program Goals:

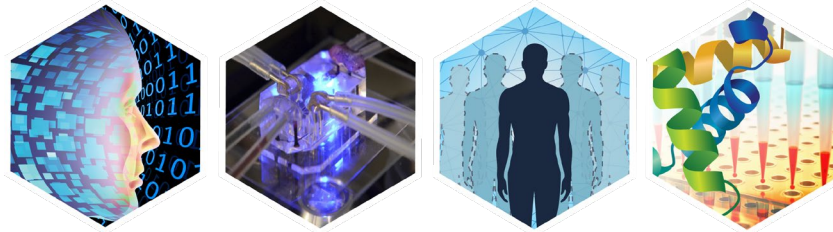
NAMs that incorporates the following features:

- 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



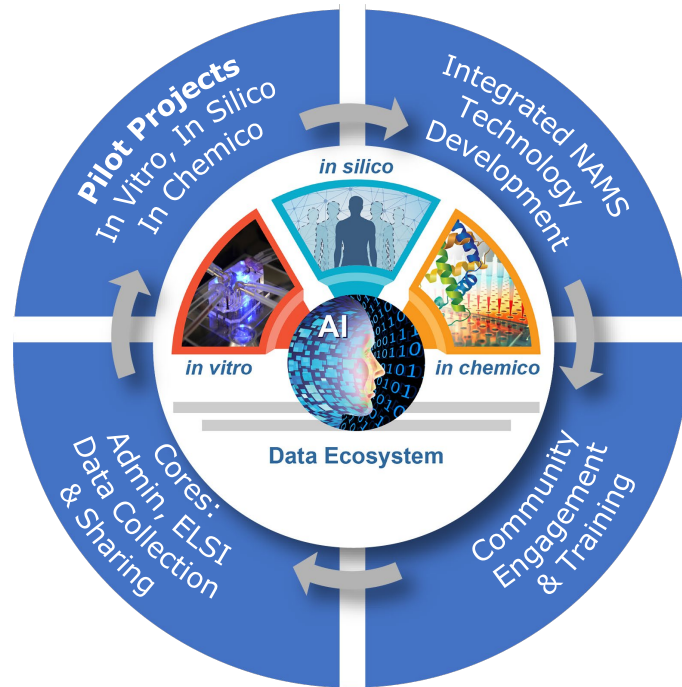
Complement-ARIE: Program Components

- **Technology Development Centers (TDC)**– stimulate the development of NAMs to fill in areas of greatest need, with emphasis on increased biological complexity and throughput, innovative combinatorial approaches, and data sharing.
- **NAMs Data Hub & Coordinating Center (NDHCC)**– create integrated data structures, including standards for model credibility, improve FAIRness (Findability, Accessibility, Interoperability, and Reusability) of NAM-relevant data, create searchable NAMs repository.
- **Validation and Qualification Network (VQN) for NAMs Adoption and Implementation** – establish common data elements and standardized reporting, apply validation/qualification frameworks, accelerate deployment and regulatory implementation of NAMs.
- **Community Engagement and Training** – *promote the development of a biomedical research workforce with the skills to build/use new NAMs, community engagement, societal and ethical considerations.*
- **Prize Competitions** - *Out-of-the-box solutions towards development, regulatory acceptance and widespread use of human-based NAMs to advance human relevance in biomedical research. 1) Ideation Stage (\$1M prize - 20 winners); 2) Reduction to Practice (\$7M prize – 3 phases)*

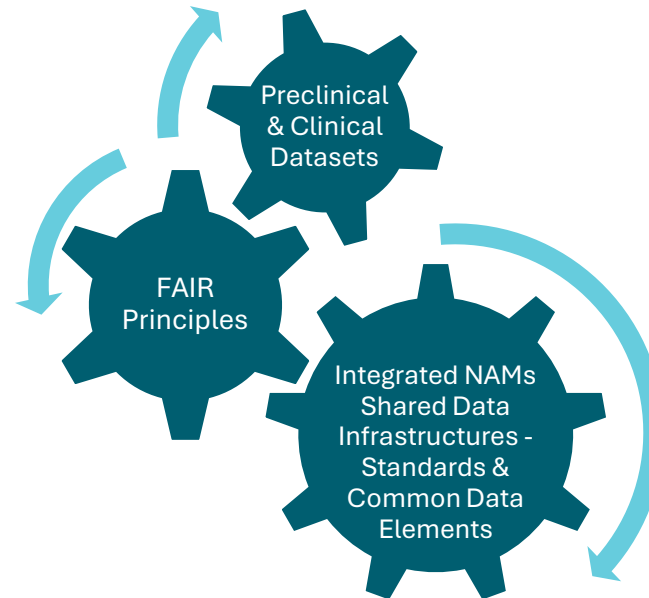


The Complement-ARIE Consortium

NAMs Tech Dev Centers (TDCs)



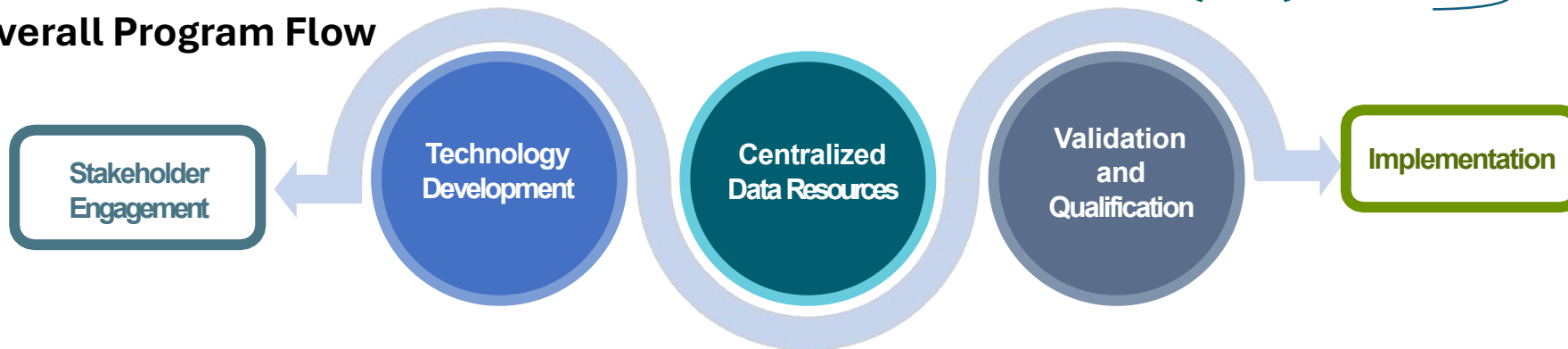
NAMs Data Hub and Coordinating Center (NDHCC)



Validation and Qualification Network (VQN) Foundation of NIH



Overall Program Flow

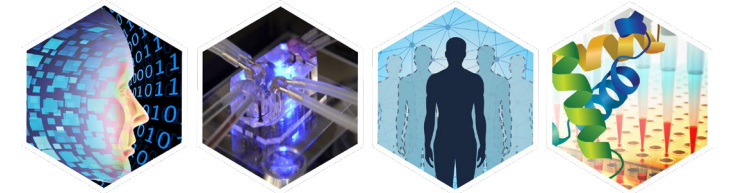


Training , Community Engagement, and Workforce Development

- Regulatory Partners
- Industry Partners
- ICCVAM/Other Agencies
- International Partners
- Non-Profits
- Other end users

Complement Animal Research in Experimentation (Complement-ARIE)

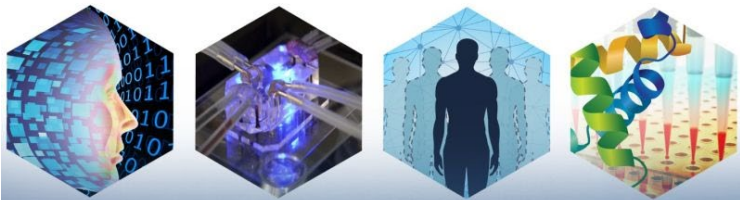
- NIH-wide, involving 27 NIH Institutes, Centers, and Offices
- Focus: development, standardization, validation and use of **human-based NAMs** to transform basic, translational, and clinical sciences
- To Date:
 - Strategic planning: listening sessions, interagency retreat, landscape analysis
 - Launch of **Validation and Qualification Network** – PPP with FNIH, design phase underway with > 60 public, industry, and non-profit partners to date
 - Established **MOUs with FDA and EPA**
 - Prize Competitions:
 - **Complement-ARIE Ideation Challenge** awarded \$1M total to 20 teams
 - **NAMs Reduction to Practice Challenge** launched; to award \$7M
- **Complement-ARIE Program Launch announced on March 18, 2026:**
 - **Technology Development Centers**
 - **NAMs Data Hub & Coordinating Center**



Read more on the
website!

NIH invests \$150 million in human-based research to reduce use of animal models

New program will develop, validate and standardize research tools to develop more sophisticated and relevant models of disease.



PROGRAM LAUNCH

Complement Animal Research
In Experimentation
(Complement-ARIE)
Research Program



FDA NEWS RELEASE

FDA Releases Draft Guidance on Alternatives to Animal Testing in Drug Development

For Immediate Release: March 18, 2026

The U.S. Food and Drug Administration today issued a [draft guidance](#) intended to help drug developers validate new approach methodologies (NAMs) to be used instead of animal testing in drug development, and to bring safe, effective drugs to market sooner based on human-centric data.

Complement-Animal Research In Experimentation (Complement-ARIE) Program Launch



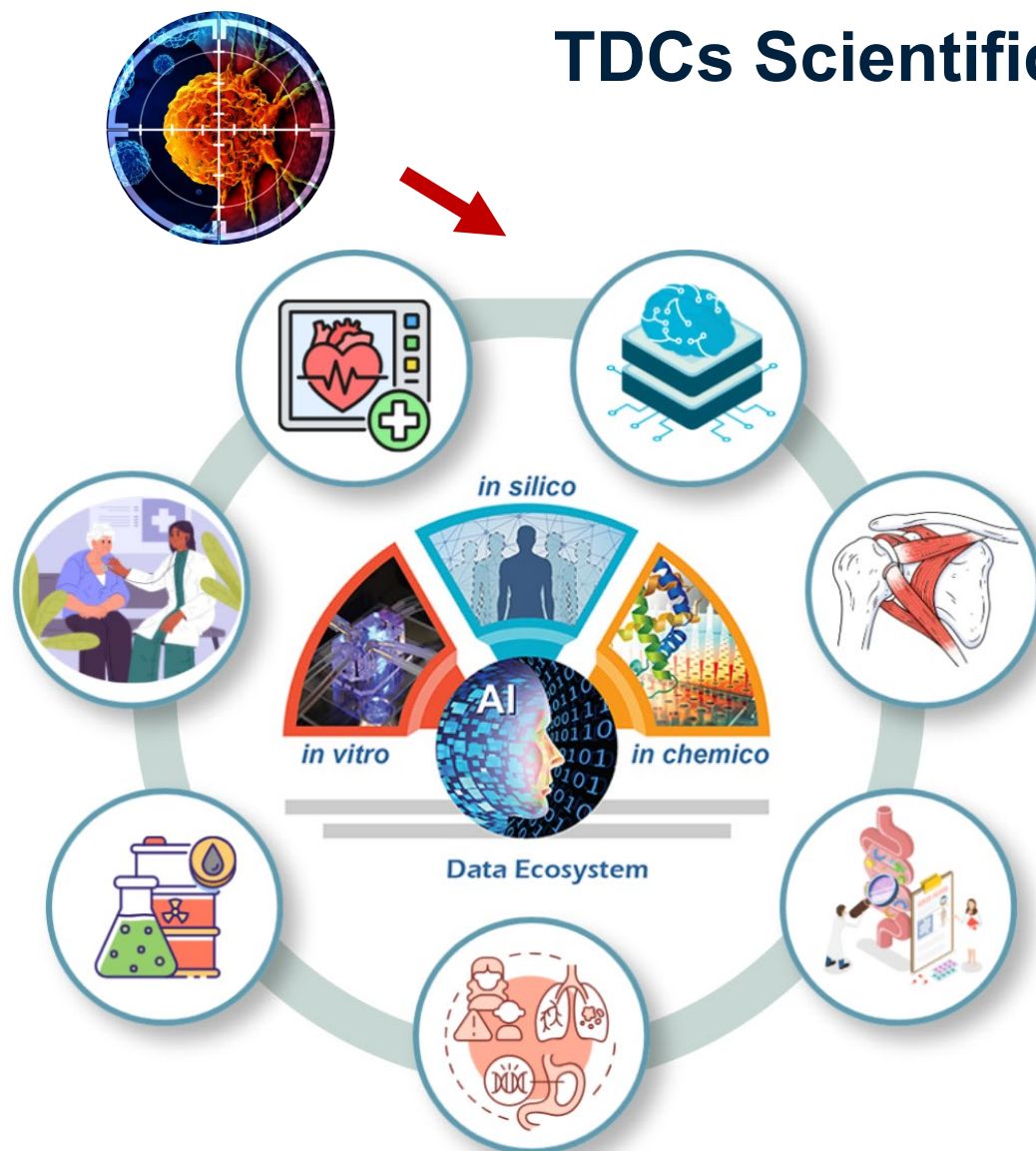
Read more
about the
TDCs and
NAM Hub

The Complement-ARIE Consortium kick-off meeting took place on May 26, 2026, to strengthen **connections and collaborations** between NIH-funded project teams and across stakeholders. There was broad engagement and attendance across government:





TDCs Scientific Topic Areas Addressed



From top of circle, moving clockwise (starting at brain image)

1. **DROIDp** - Johns Hopkins University, Baltimore led by Lena Smirnova, Ph.D.
2. **Musculoskeletal** - Brigham and Women's Hospital, Boston led by Shrike Zhang, Ph.D.
3. **Gastrointestinal** - Cincinnati Children's Hospital Medical Center led by James M. Wells, Ph.D.
4. **3D-MOFIB** - NIH's NCATS led by Marc Ferrer, Ph.D.
5. **Chemical Safety** - Texas A&M AgriLife Research, College Station led by Ivan Rusyn, M.D., Ph.D.
6. **Gynecology** - Massachusetts Institute of Technology, Cambridge led by Linda Griffith, Ph.D. – co-funded by ORWH
7. **Cardiac** - Stanford University, Palo Alto led by Joseph C. Wu, M.D., Ph.D.
8. **Precision Oncology** – University of Texas, MD Anderson Cancer Center led by Xiling Shen, Ph.D. - co-funded by ORIVA and NCI

Complement-ARIE NAMs Reduction to Practice Challenge

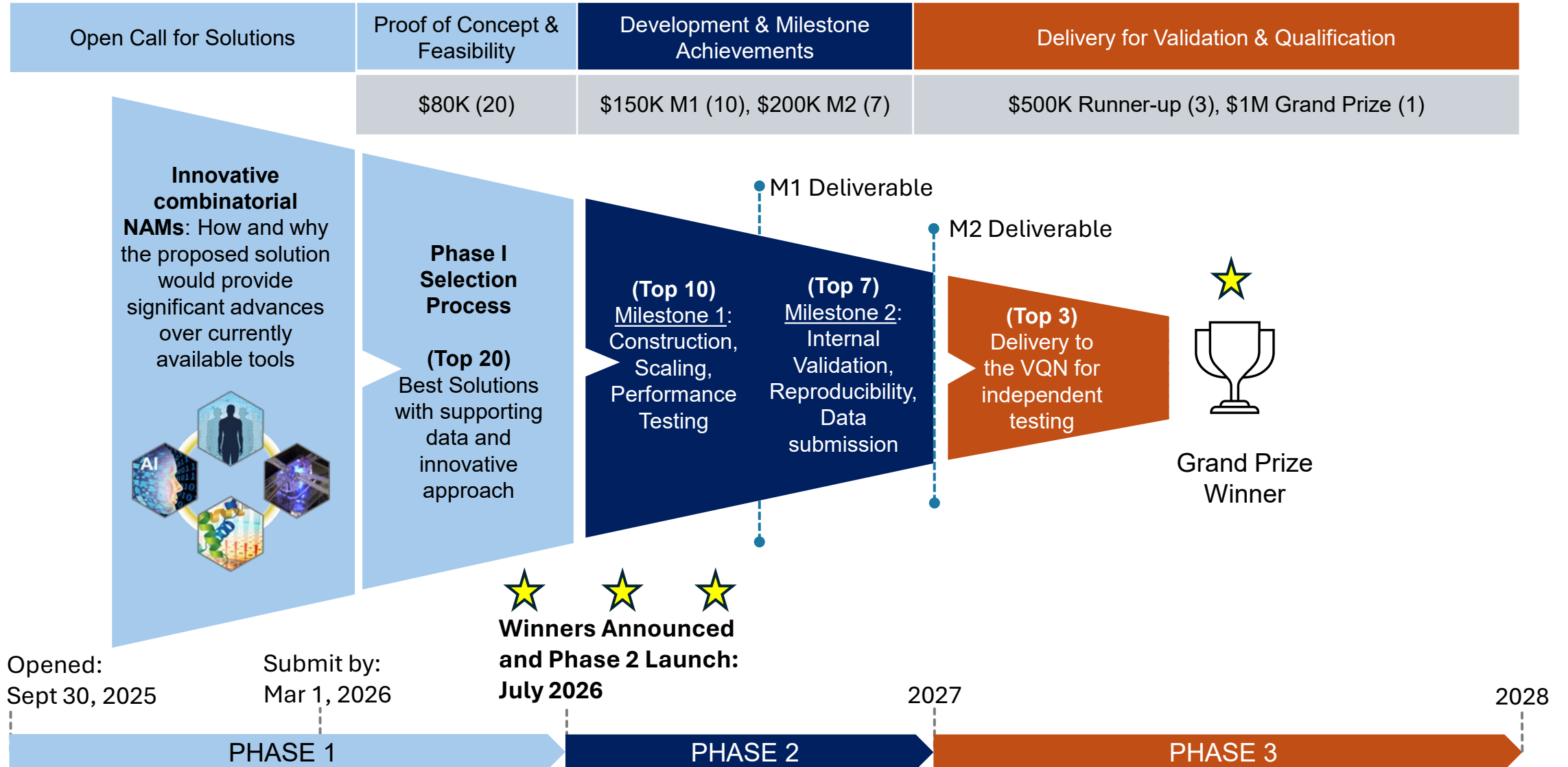
The NIH Common Fund has launched the **Complement-ARIE NAMs Reduction to Practice Challenge**, a prize competition that invites innovative New Approach Methodologies (NAMs) solutions from teams who can successfully demonstrate implementation of integrated human-based solutions in a practical and usable form within a three-year period. This is a three-phase challenge:

- ✓ **Phase 1: Proof of Concept and Feasibility Studies:**
- **Phase 2: Prototype Development and Milestone Achievements:**
- **Phase 3: Prototype Delivery for Validation and Qualification:**

The total cash prize purse for this competition is \$7,000,000 to be shared among the winners

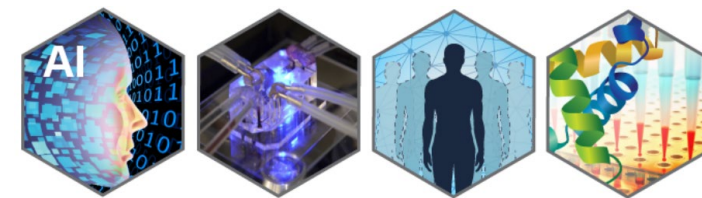
Twenty RTP Challenge Phase 1 winners were announced, and Phase 2 was launched on July 20, 2026.

Complement-ARIE NAMs Reduction to Practice (RTP) Challenge



Validation and Qualification Network (VQN)

- The Complement-ARIE Program has partnered with the Foundation for the National Institutes of Health (FNIH) to establish the **Validation and Qualification Network (VQN)**
- VQN goals:
 - Accelerate the implementation and adoption of NAMs in research and regulatory contexts by **ensuring NAMs are robust, reliable, and reproducible**
 - Demonstrate **biological relevance and establish confidence in NAMs** to ensure each NAM is “fit for purpose”
 - Multi-pronged approach:
 - Establish common data elements and standardized reporting
 - Ensure NAMs have well-described protocols
 - Design and fund transferability studies
 - Conduct quality assessment
- **FNIH solicited submissions of well-developed NAMs on rolling basis**



Learn more at
FNIH.org/VQN

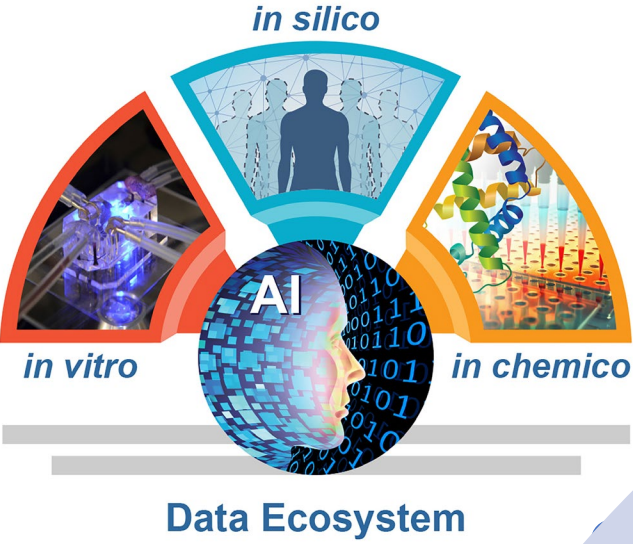
List of Currently Participating Organizations

Public-Sector Partners (20)

- Advanced Research Project Agency-Health
- Biomedical Advanced Research and Development Authority
- Biotechnology Industry Research Assistance Council (BIRAC) **(India)**
- Consumer Product Safety Commission
- Department of Defense Congressionally Directed Medical Research Program
- Defense Threat Reduction Agency
- Environmental Protection Agency
- European Commission **(E.U.)**
- Food and Drug Administration
- Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM)
- India Council of Medical Research **(India)**
- National Aeronautics and Space Administration
- National Centre for the Replacement, Refinement, and Reduction of Animals in Research (NC3Rs) **(UK)**
- National Institutes of Health
- National Institute of Health Sciences **(Japan)**
- National Institute of Standards and Technology
- National Science Foundation
- Pharmaceuticals and Medical Devices Agency **(Japan)**
- US Department of Agriculture
- Veterans Administration

Private-Sector Partners (43) (Industry & Nonprofit)

- Alternatives Research and Development Foundation
- American Chemistry Council
- Americans for Medical Progress
- American Type Culture Collection
- Ananda Devices Inc.
- Animal Welfare Institute
- AstraZeneca
- Asymmetrex
- BioIVT
- Charles River Laboratories
- CN Bio
- Critical Path Institute
- Draper
- Eyescreen, Inc.
- GlaxoSmithKline
- Health and Environmental Sciences Institute
- Hesperos
- Humane World for Animals
- Humane World for Animals International
- Humble Alliance L3C
- IBM
- Institute for Invitro Sciences
- International Collaboration on Cosmetics Safety
- International Foundation for Ethical Research
- International Society for Stem Cell Research
- JRF Global
- Labcorp
- Mattek
- Mimetas
- Novo Nordisk
- Physicians Committee for Responsible Medicine
- Precision Quantomics
- Radahaim
- Sanofi
- Spanios
- SRI international
- The 3Rs Collaborative
- The Jackson Laboratory
- TheWell Bioscience
- Toxys
- UCB
- Unilever
- Vivodyne



etc.



Biomedical
Research

The NAMs Confidence Continuum:
from *Biomedical Research* to
Toxicological Application and
Regulatory Implementation

Questions/Discussion

To learn more about Complement-ARIE Program, visit:
<https://commonfund.nih.gov/complementarie>

Reach out to us: complement-arie@od.nih.gov

Join the Complement-ARIE listserv: go.nih.gov/ComplementARIE_listserv