

CATALYZING THE DEVELOPMENT AND USE OF NOVEL ALTERNATIVE METHODS (NAMS) TO ADVANCE BIOMEDICAL RESEARCH

Overview of Recommendations from the NIH Advisory
Committee to the Director Working Group

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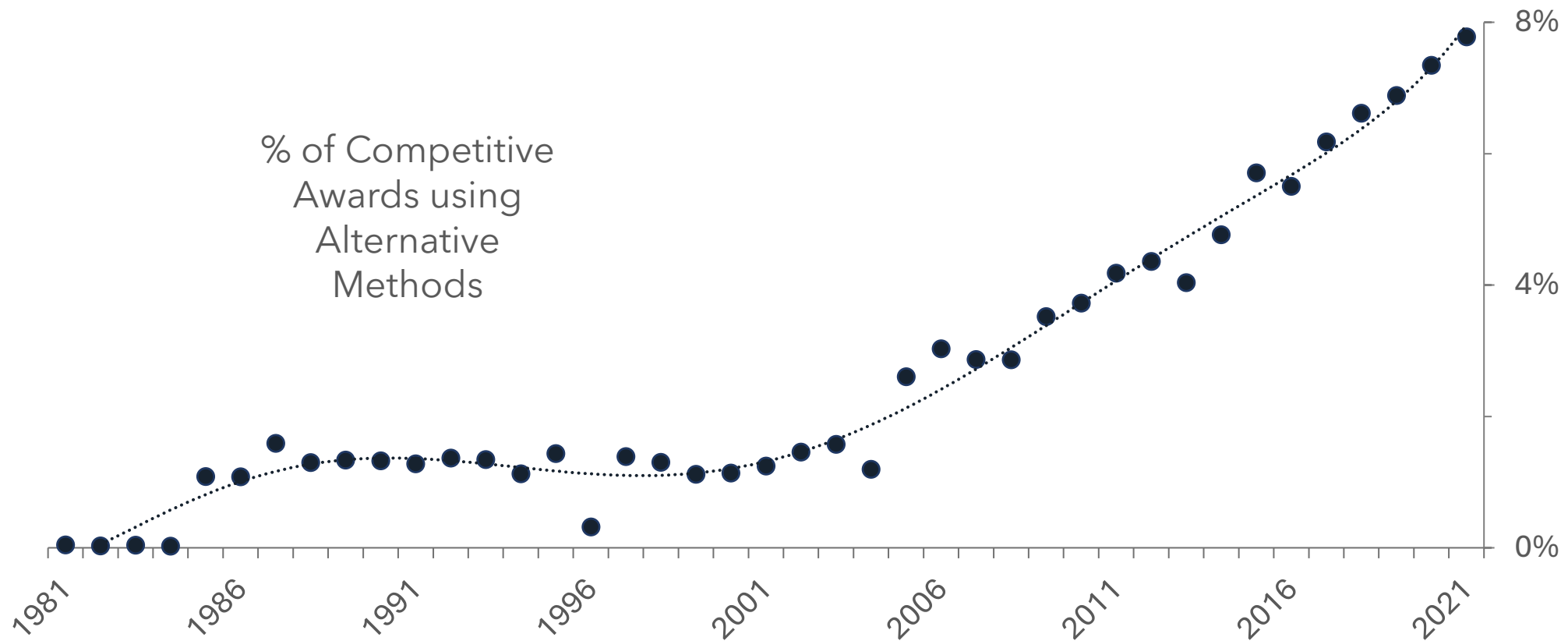
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ICCVAM PUBLIC FORUM

MAY 21, 2024

IMPETUS FOR EFFORT

Growing NIH Investment in Alternatives



**Does not include clinical research*

NAMS WORKING GROUP CHARGE

Catalyze the Development and Use of NAMs

- Identify the types of alternative methods and assess their general strengths and weaknesses for studying human biology, circuits, systems, and disease states
- Characterize the types of research, condition, or disease for which NAMs are most applicable or beneficial
- Articulate high-priority areas for NIH investment in the **use and development with human applicability** to:
 - Advance progress into understanding specific biological processes or states
 - Augment the tools and capabilities for biomedical research to complement and/or potentially replace traditional models

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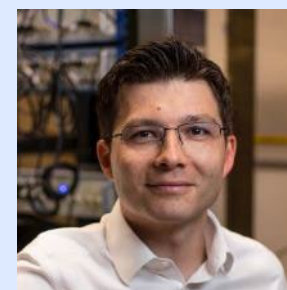
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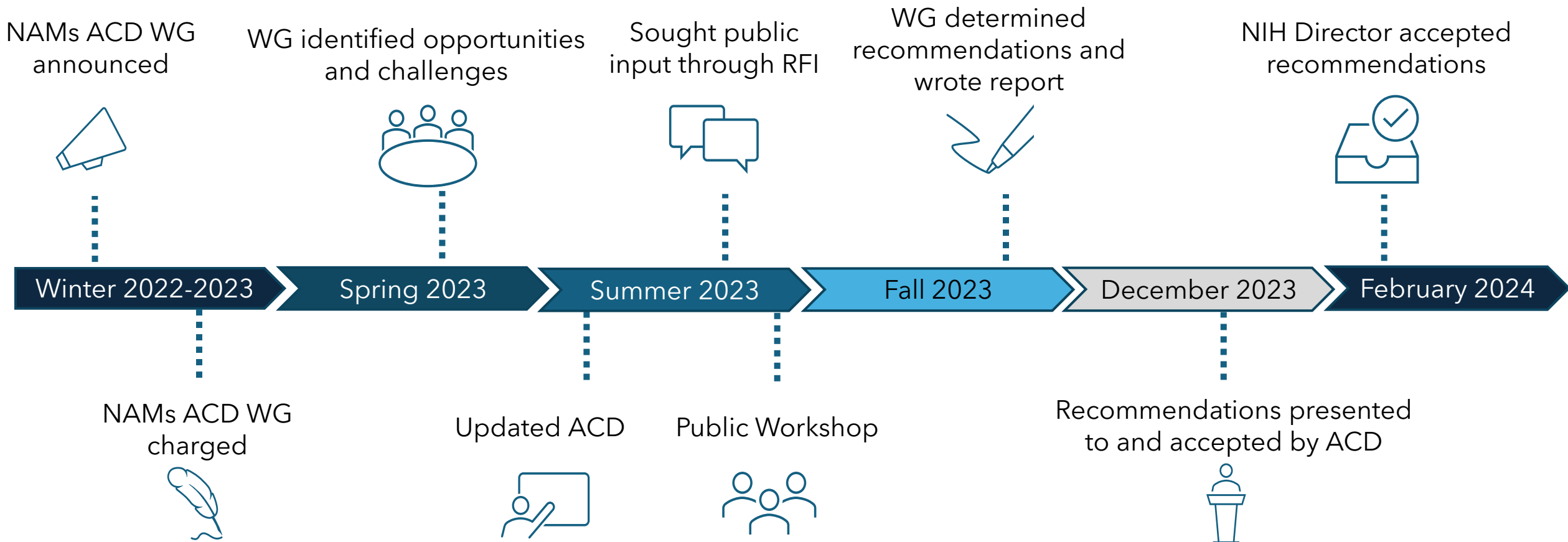
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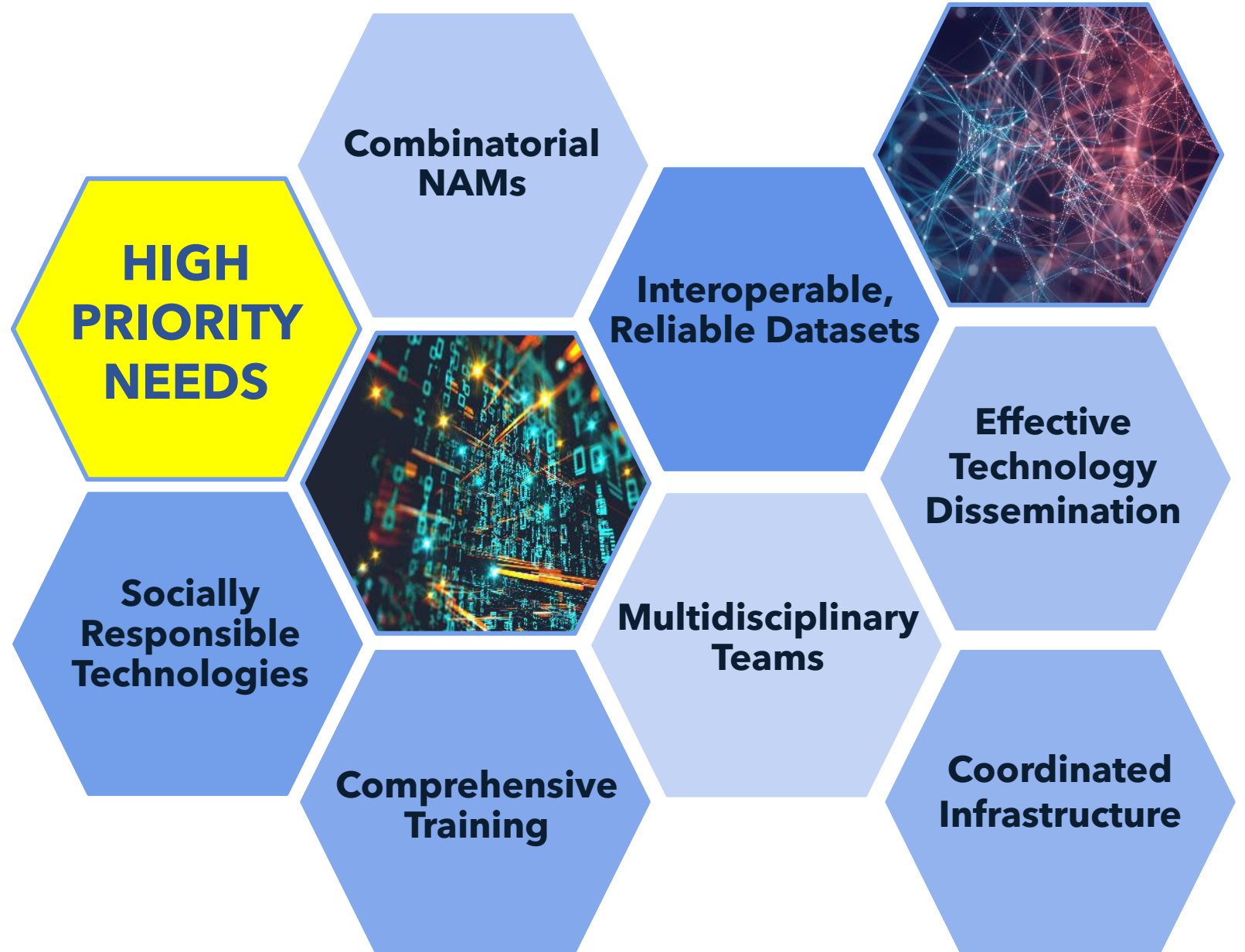
TIMELINE OF ACTIVITIES

Gathering Data and Seeking Input



WHAT WE HEARD

Importance of Integration



Recommendations to Catalyze the Development and Use of NAMs

1

Prioritize the development and use of combinatorial NAMs

2

Establish resources, infrastructure, and collaborations to promote the use of interoperable, reliable, and well curated/high quality datasets produced from research using NAMs

3

Promote effective dissemination and interconnection of NAMs technologies

4

Invest in comprehensive training to bolster continuous advances in NAMs development and use

5

Facilitate multidisciplinary teams with expertise across technologies and the lifecycle of NAMs development and use

6

Promote social responsibility in both the creation and deployment of NAMs across the research lifecycle

7

Support and maintain coordinated infrastructure to catalyze effective and responsible NAM development and use

RECOMMENDATION 1

**Prioritize the
development and use of
combinatorial NAMs**

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- Technology combinatorial effect, a phenomenon where the integration or combination of different technologies or their components results in a more significant impact than the sum of their individual effects
 - Strategic combination of NAMs can lead to breakthroughs not possible with any single NAM

RECOMMENDATION 2

Establish resources, infrastructure, and collaborations to promote the use of interoperable, reliable, and well curated/high quality datasets produced from research using NAMs

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- Reliable and interoperable *high-quality* datasets are needed for appropriate validation or qualification of NAMs
 - Data and associated metadata should be generated both from NAMs and traditional approaches
 - High-quality data increases overall efficiency, reproducibility, and validity of comparisons

RECOMMENDATION 3

Promote effective dissemination and interconnection of NAMs technologies

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- Effective and rapid technology dissemination requires NAMs developers to consider users through development process
 - Successful deployment requires clarity regarding technology “maturity” for use and dissemination
 - Importance of designing to be “fit for purpose”

RECOMMENDATION 4

**Invest in
comprehensive training
to bolster continuous
advances in NAMs
development and use**

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- Technology dissemination is necessary but not sufficient - need to support skills/knowledge to use them appropriately
 - Particular focus on ensuring equity both in terms of institution, career stage, and role in the process
 - Key to success is integrated and interdisciplinary collaboration

RECOMMENDATION 5

**Facilitate
multidisciplinary teams
with expertise across
technologies and the
lifecycle of NAMs
development and use**

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- Collaboration is needed across multiple sectors, disciplines, and expertise across lifecycle of development
 - Incentives are lacking for integrating cross-disciplinary research with implementation in mind
 - Different lexicon and approaches creates barriers to communication across fields and sectors

RECOMMENDATION 6

Promote social responsibility in both the creation and deployment of NAMs across the research lifecycle

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- Trust throughout the lifecycle of NAMs development and use is required to promote uptake
 - Ethical considerations must be considered upfront to ensure inequities are addressed, both in terms of design and ultimate access and cost
 - The opportunity is clear – caution is needed to ensure hyperbolic narrative doesn't derail efforts

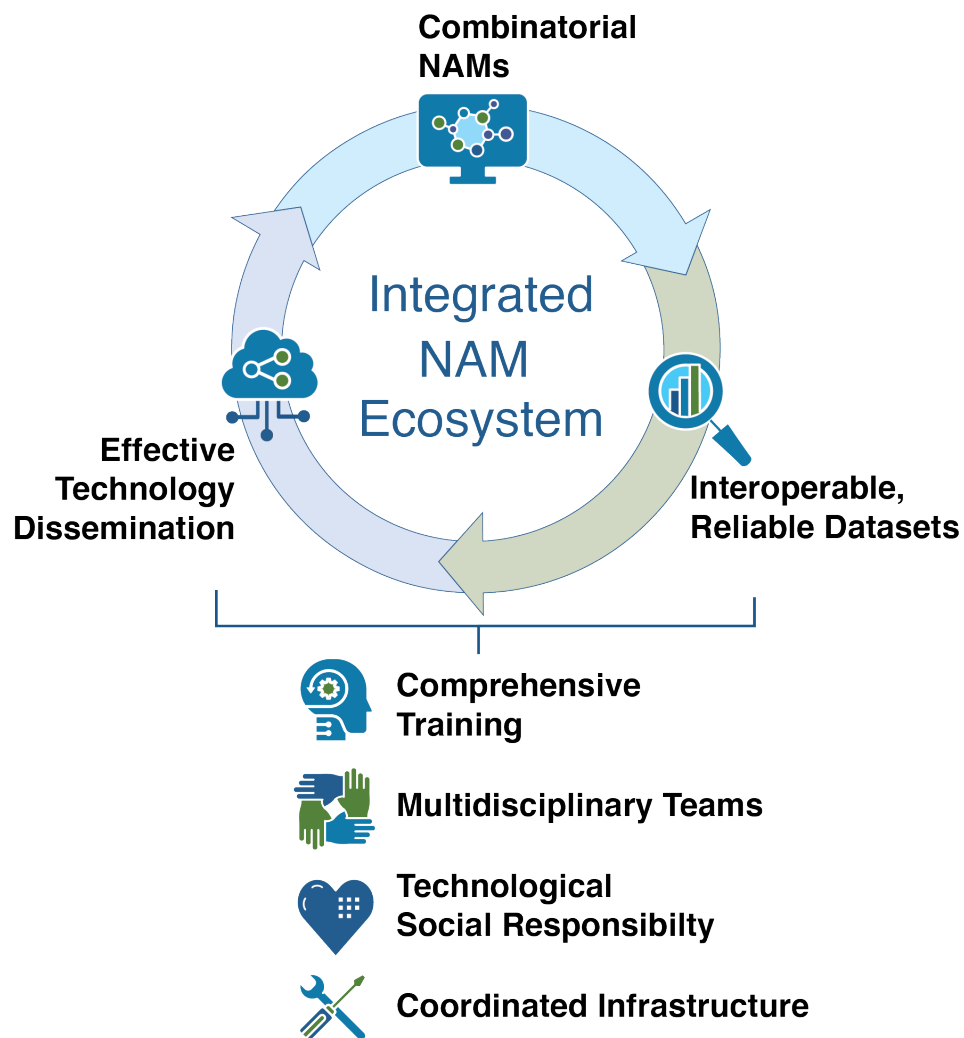
RECOMMENDATION 7

Support and maintain coordinated infrastructure to catalyze effective and responsible NAMs development and use

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- There is a clear need for dedicated resources and venues to support NAMs
 - Venues for communication and collaboration:
 - Create organic environments for common language and standards
 - Reduce redundancy to maximize investment
 - Spur new collaborations for integrated approaches

THE VISION

An integrated ecosystem to catalyze scientific discovery



OUTLOOK

Implementation Planning & Next Steps

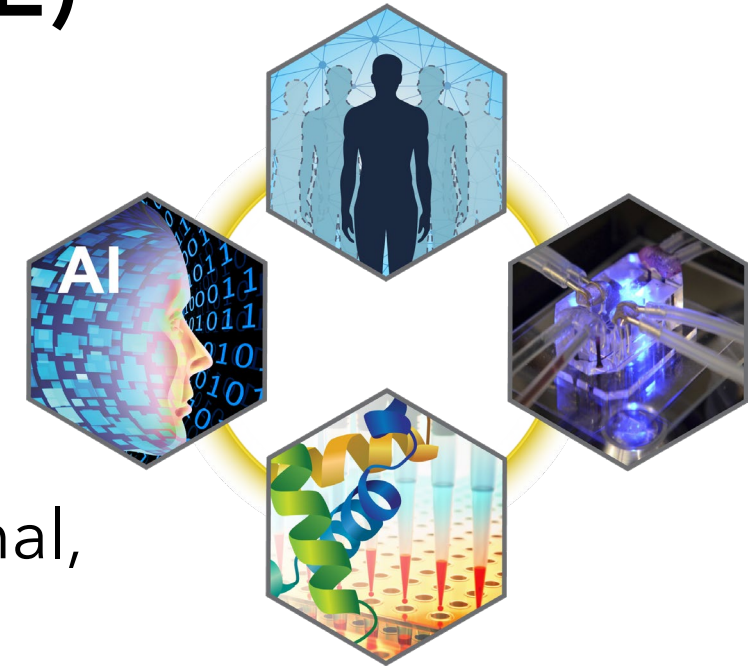


- The NIH Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) is leading implementation of the recommendations. To date, DPCPSI has:
 - Conducted a prioritization and feasibility analysis of all recommendations and sub-recommendations
 - Identified lead ICOs for each item
 - Held meetings and discussions with the most heavily involved offices and programs, including ICCVAM
- As next steps, DPCPSI will:
 - Develop metrics of success and processes to tracking them
 - Engage all ICs, including through an NIH-wide data call
 - Ultimately, provide an update to the ACD in December

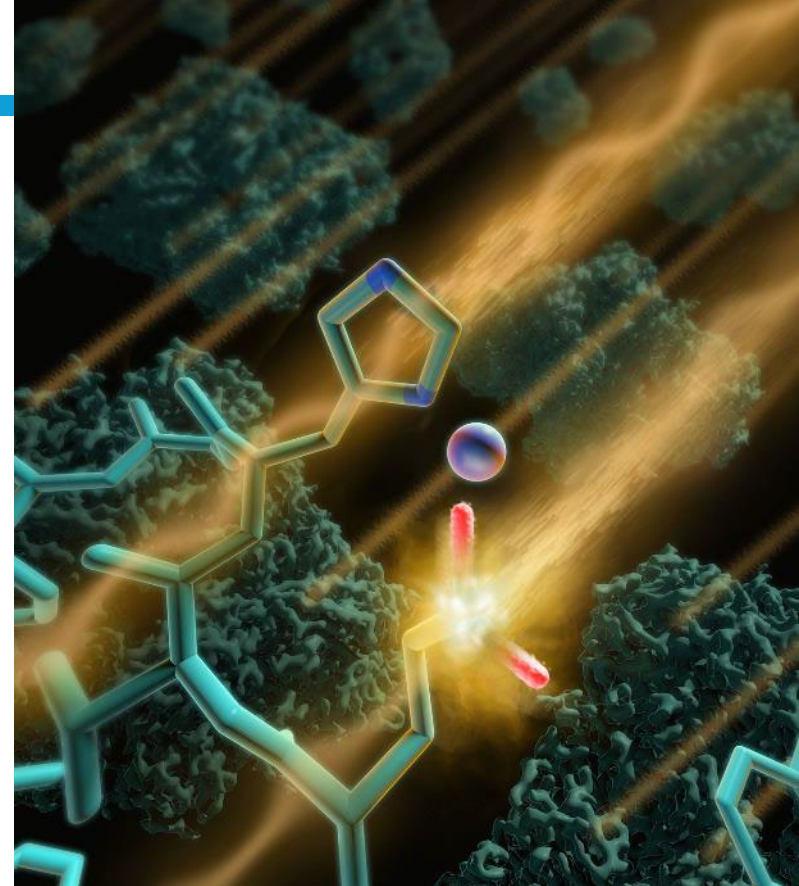
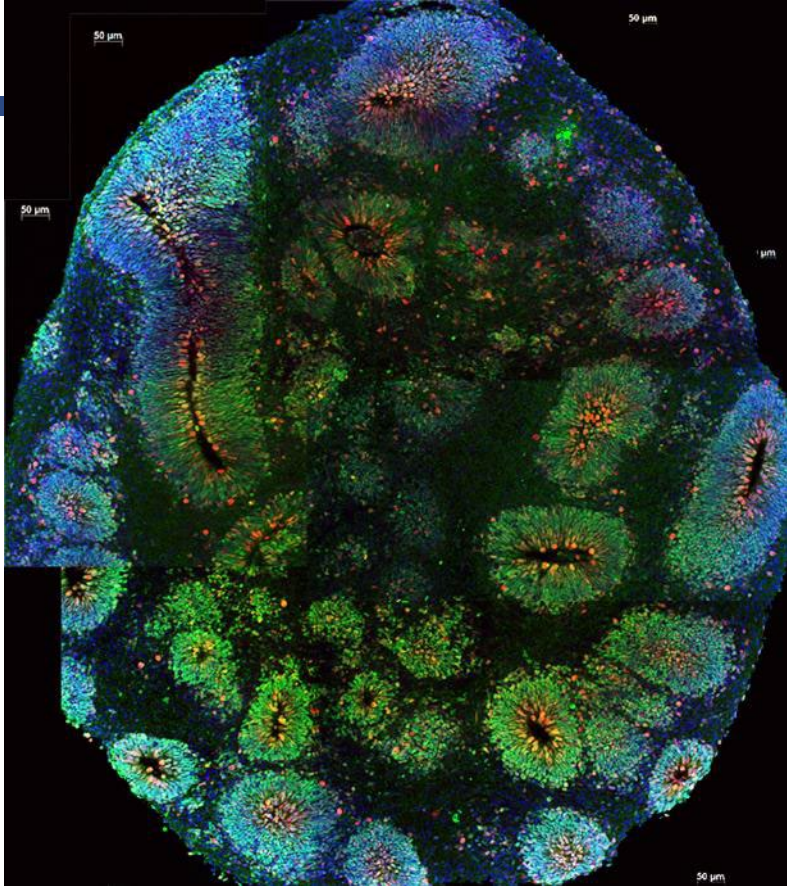
PREVIEW OF PROGRESS SO FAR

Complement Animal Research in Experimentation (Complement-ARIE)

- Aligned with the ACD recommendations and approved by Council of Councils in January 2024
- Mission 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.
- Activities:
 - Three listening sessions with major collaborators
 - Federal interagency retreat Oct 19-20, 2023 at NIH
 - Complement-ARIE Ideation Challenge prize winners announced!
 - Exploring public-private partnerships



Link to Complement-ARIE Challenge
winner announcement



DISCUSSION