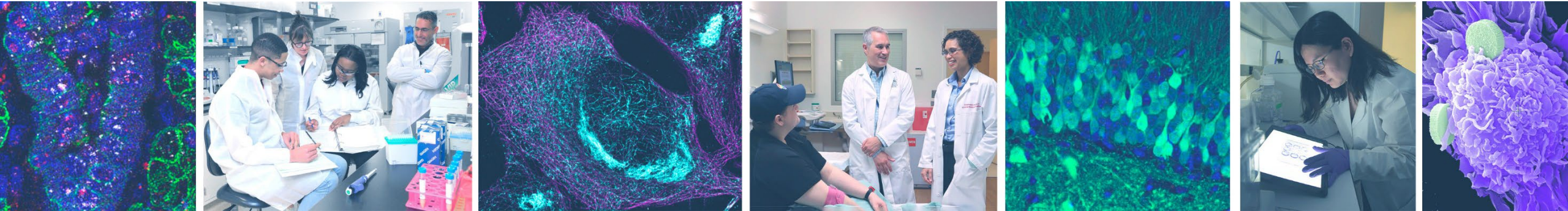


Director's Report

128th Advisory Committee to the Director Meeting
June 13, 2024



Monica M. Bertagnoli, MD
Director, National Institutes of Health



Topics for Today

- NIH Leadership Changes
- Awards
- Events
- Follow up to ACD Working Groups
- Programs and Initiatives
- Science Highlights



NIH Leadership Changes

Director, Fogarty International Center



Kathleen M. Neuzil, MD

Director, Center for Information Technology



Sean Mooney, PhD

Departure, NIMH Director



Josh Gordon, MD, PhD

Awards

Presidential Rank Award



**Keith Lamirande, MBA
NCATS**



**Colleen McGowan, MHA
ORS**

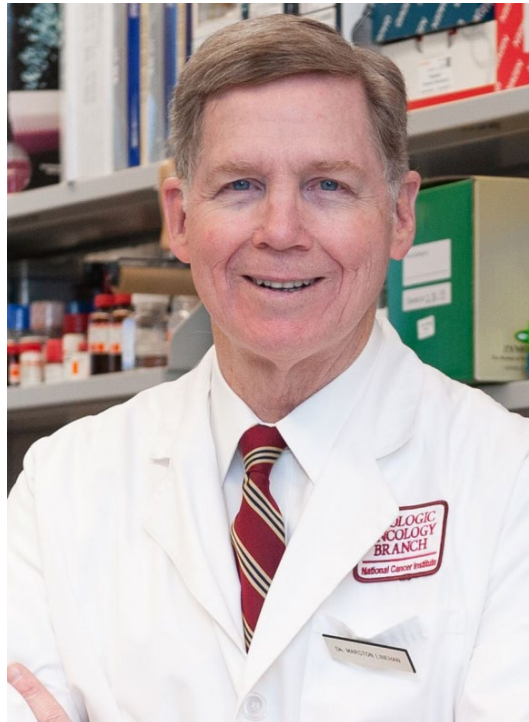


**Camille Hoover, MSW
NIDDK**



**Jerry Sheehan, MS
NLM**

Secretary's Award for Distinguished Service



W. Marston Linehan, MD

HHS Career Achievement Award



Andre Nussenzweig, PhD

Secretary's Award for Meritorious Service



Brigitte C. Widemann, MD



Events

POTUS visits NIH Pharmacy



White House Demo Day



10th Annual Global Health Workshop with Gates Foundation



White House Initiative on Women's Health Research Roundtable in Atlanta

WHITE HOUSE INITIATIVE ON WOMEN'S HEALTH RESEARCH



WHITE HOUSE INITIATIVE ON WOMEN'S HEALTH



Valerie Montgomery Rice
Professor, School of Medicine

First Lady Jill Biden

Ms. Maria Toler
Executive Director, Healthy Women

WHITE HOUSE INITIATIVE



Trips



Vint Cerf Ral Cultural Lecture AI in Biomedical Research



Clinical Center Exhibit for Nobel Laureate Dr. Harvey Alter



Follow up to ACD working groups

- Postdoctoral Training
- Disability
- Novel Alternative Methods

Updates on advancing postdoctoral training

Recommendations
from the NIH ACD WG



Changing the Way We *Value* Postdoctoral Scholars

Enhancing NRSA Stipends and Benefits

- Informed by the ACD Postdoc WG, NIH is implementing the **largest increase in postdoctoral stipends in recent history**

FY24 Stipends for NRSAs	\$28,224 (4%) Predocs	\$61,008 (8%) Postdocs	
FY24 Benefits	\$4,750 Predoc TRE/IA	\$12,400 Postdoc TRE/IA	\$3,000 Childcare

- NIH is committed to reaching the recommended \$70,000 stipend level over the next 3-5 years, as appropriations allow

Changing the Way We *Talk About* Postdoctoral Scholars

Terminology Change: Postdoctoral Scholars

Definition of "Postdoctoral Scholar": An individual who has received a doctoral degree or equivalent working in a term-limited position of mentored research and professional development to prepare for an independent career usually in research and teaching.

- Standard definition to prevent "gaming" of shifting postdoctoral scholars to another position, in title only, with no meaningful modification to their role, compensation, or benefits.

Changing the Way We *Engage* Postdoctoral Scholars

Gathering Public Input to Inform Implementation

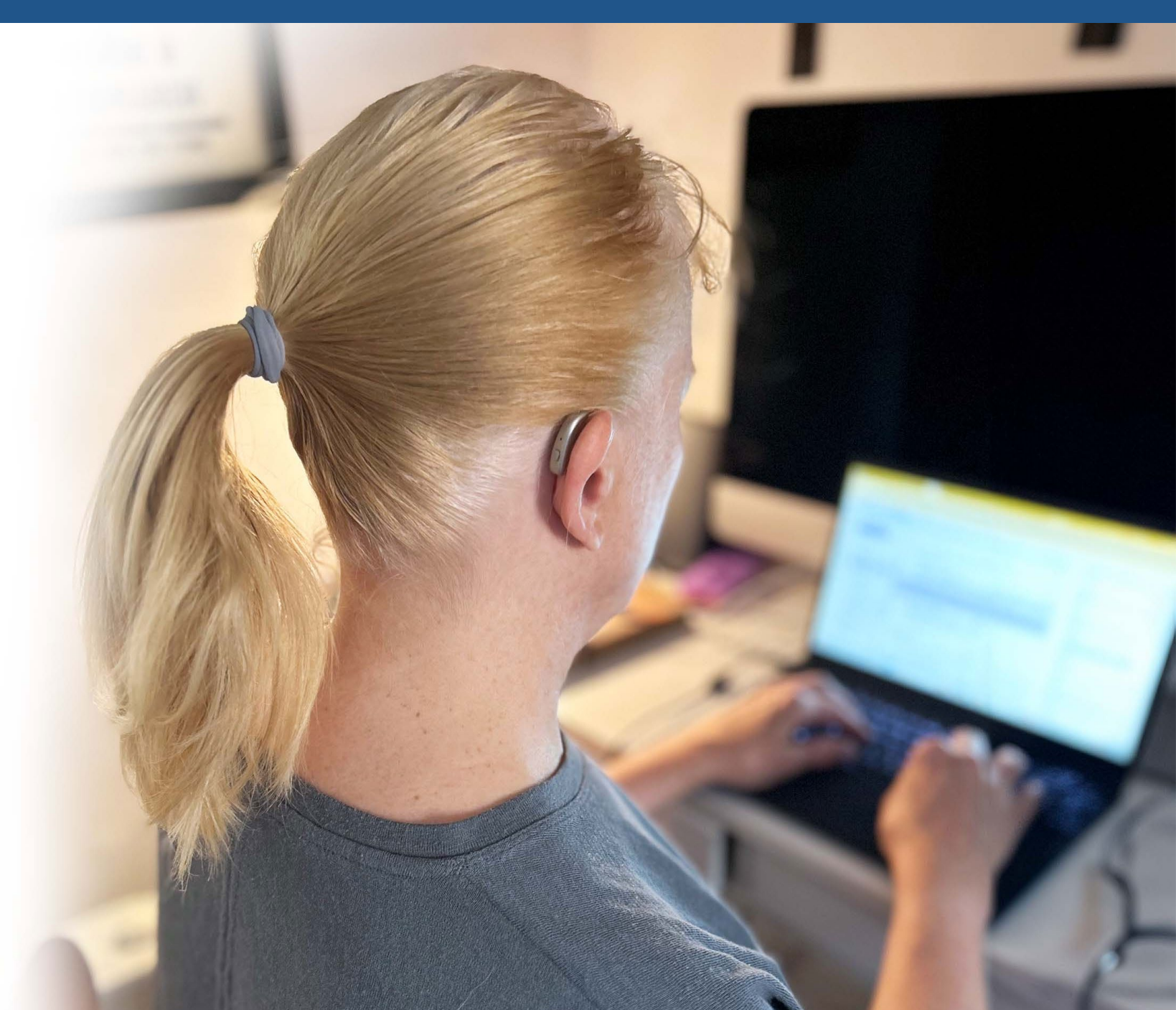
- Finalizing RFI to gain public input on how best to implement ACD WG recommendations
- Developing implementation teams to address high priority ACD WG recommendations such as:

Create and expand mechanisms to support the full talent pool of postdoctoral scholars

Facilitate the transition of postdoctoral scholars into the next career stage, including roles beyond academic faculty

Promote training and professional development of postdoctoral scholars and their mentors

Disability



Updating the NIH Mission Statement

- NIH Advisory Committee to the Director (ACD) WG on Diversity's Subgroup on Individuals with Disabilities recommendations (December 2022)
 - *Recommendation to **remove language of "reducing disability"** from the NIH mission statement*

Current mission statement

- To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

Proposed revised mission statement

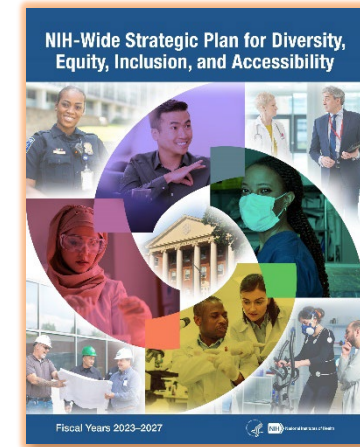
- To seek fundamental knowledge about the nature and behavior of living systems and **to apply** that knowledge to **optimize health and prevent or reduce illness for all people.**

Updating the Mission Statement: Request for Information (RFI)

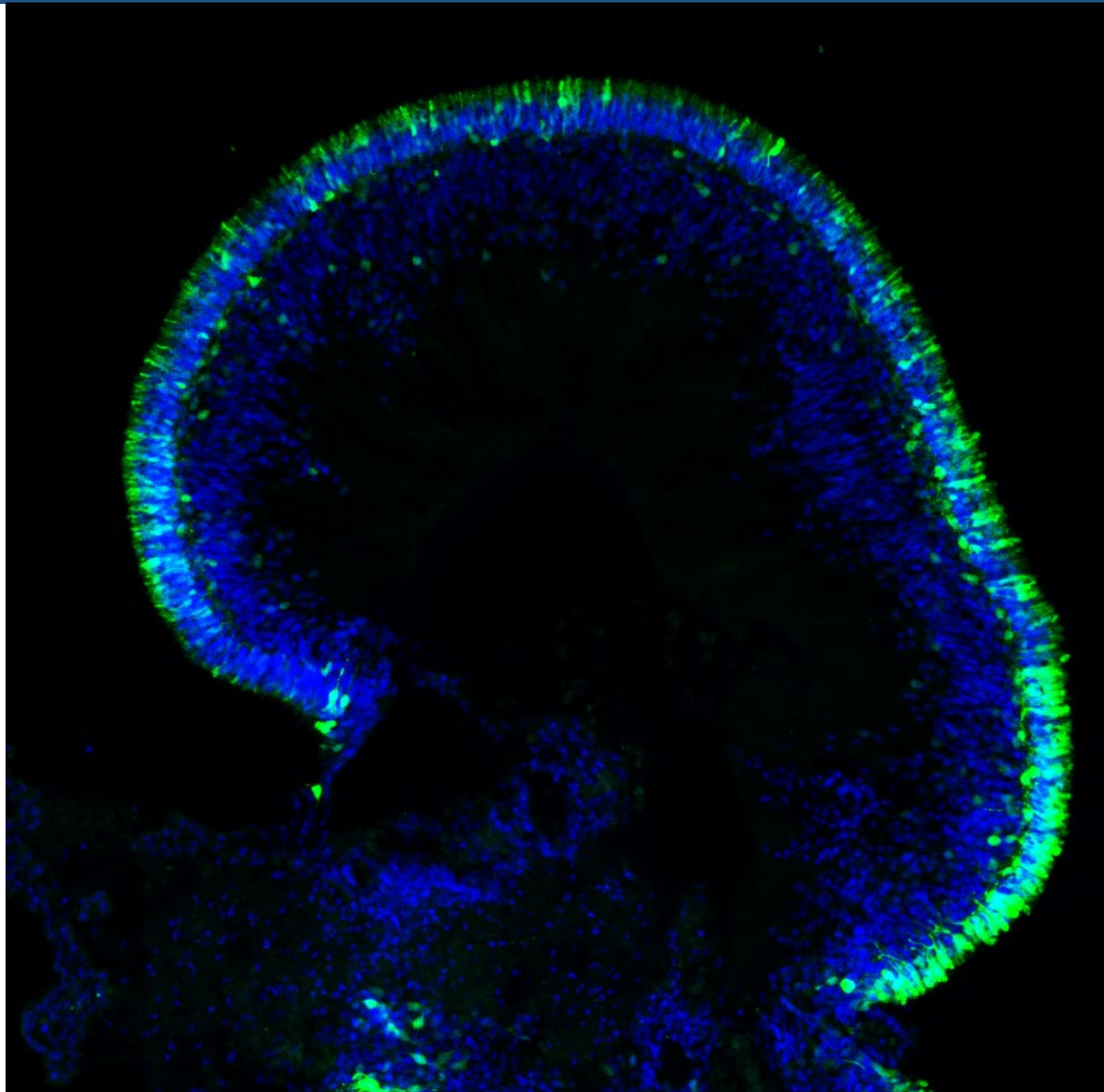
- Released RFI to gather internal and external input
- Received 480 total responses
 - Public report on RFI will be posted in coming weeks
- Strong, opposing views expressed in RFI
 - 40%: add “disability” back into the statement in some way
 - Develop an alternative way to include disability
 - Keep “reduce disability”
- RFI indicated **more input needed** to better understand all perspectives before finalizing a new mission statement
 - **Next steps:** additional community engagement

Disabilities Research across NIH

- NIH Advisory Committee to the Director (ACD) **Working Group on Diversity's Subgroup on Individuals with Disabilities** recommended (December 2022) conducting research on disability health and health care disparities and equity
- Steering Committee DEIA Working Group established **Disabilities Subcommittee** in 2024 to coordinate and consult on activities related to NIH DEIA Strategic Plan
- DPCPSI is bringing on a **Senior Leader to support NIH-wide activities** on disabilities research
- Close coordination with NIMHD on activities

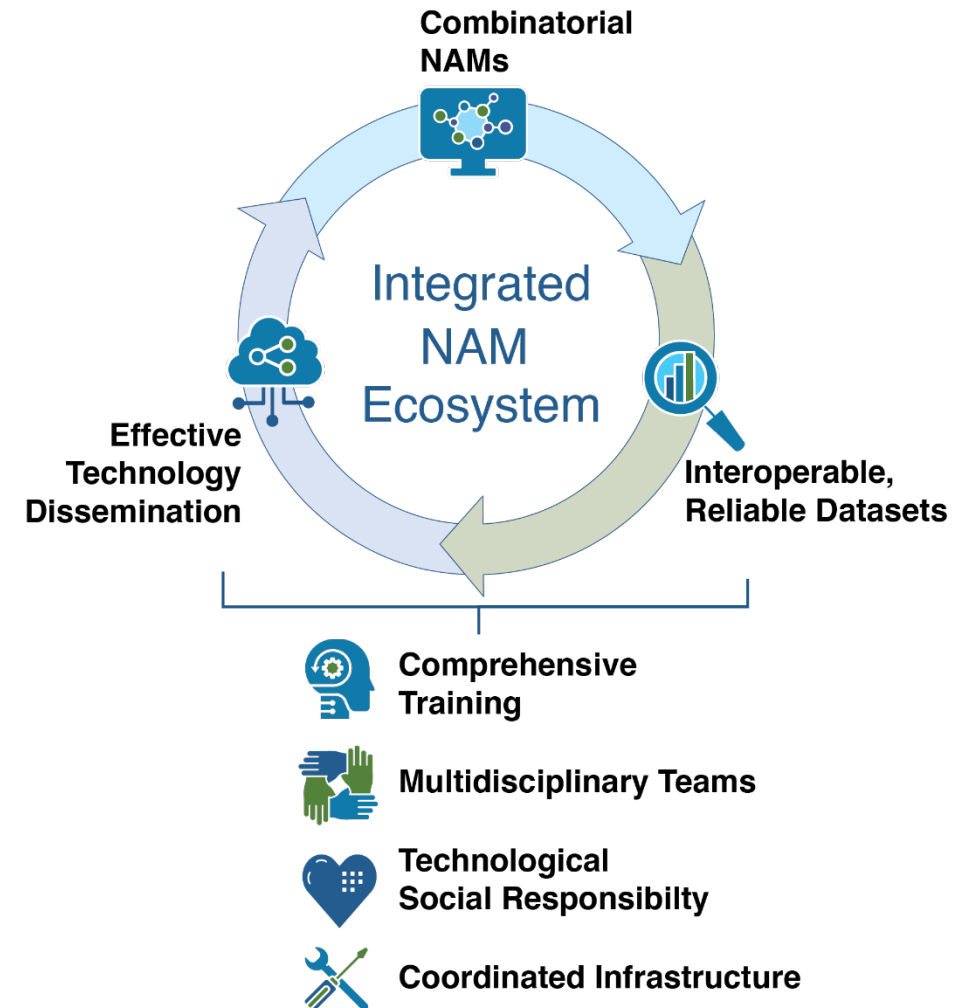


Novel Alternative Methods



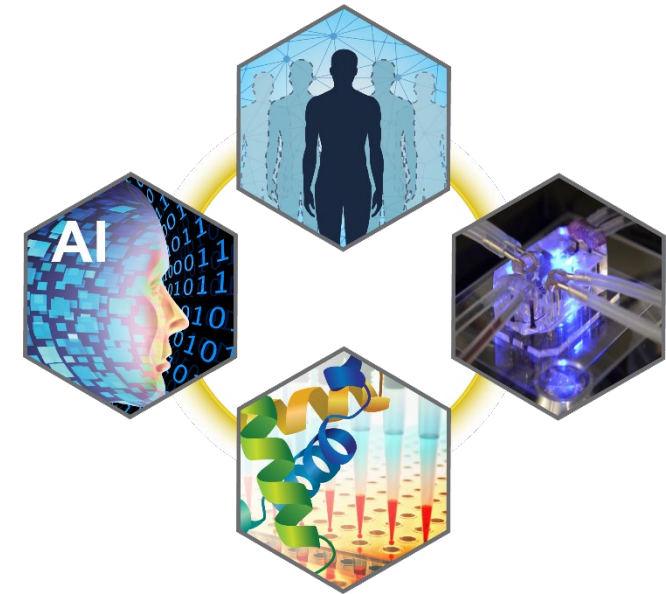
Catalyzing the Development and Use of New Approach Methods (NAMs)

- WG issued recommendations and ACD accepted in December 2023
- NIH Director accepted in February 2024
- Set forth a vision for an integrated ecosystem to catalyze scientific discovery
- Implementation in progress
 - Conducted prioritization and feasibility analysis
 - Identified lead ICOs for each item
 - Ongoing NIH-wide data call + targeted discussions with most heavily involved ICOs



Complement Animal Research in Experimentation (Complement-ARIE)

- Approved by Council of Councils in January 2024 and includes representation from 23 ICOs
- 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
- Strategic planning activities:
 - Three listening sessions + federal interagency retreat
 - **Complement-ARIE Ideation Challenge Prize Competition**
 - Solicited entries for new methods and approaches in NAMs
 - \$1M total awarded to 20 diverse teams for insight about innovation and investment opportunities
 - Exploring public-private partnerships with FNIH



Link to Complement-ARIE Challenge
winner announcement

Programs and Initiatives

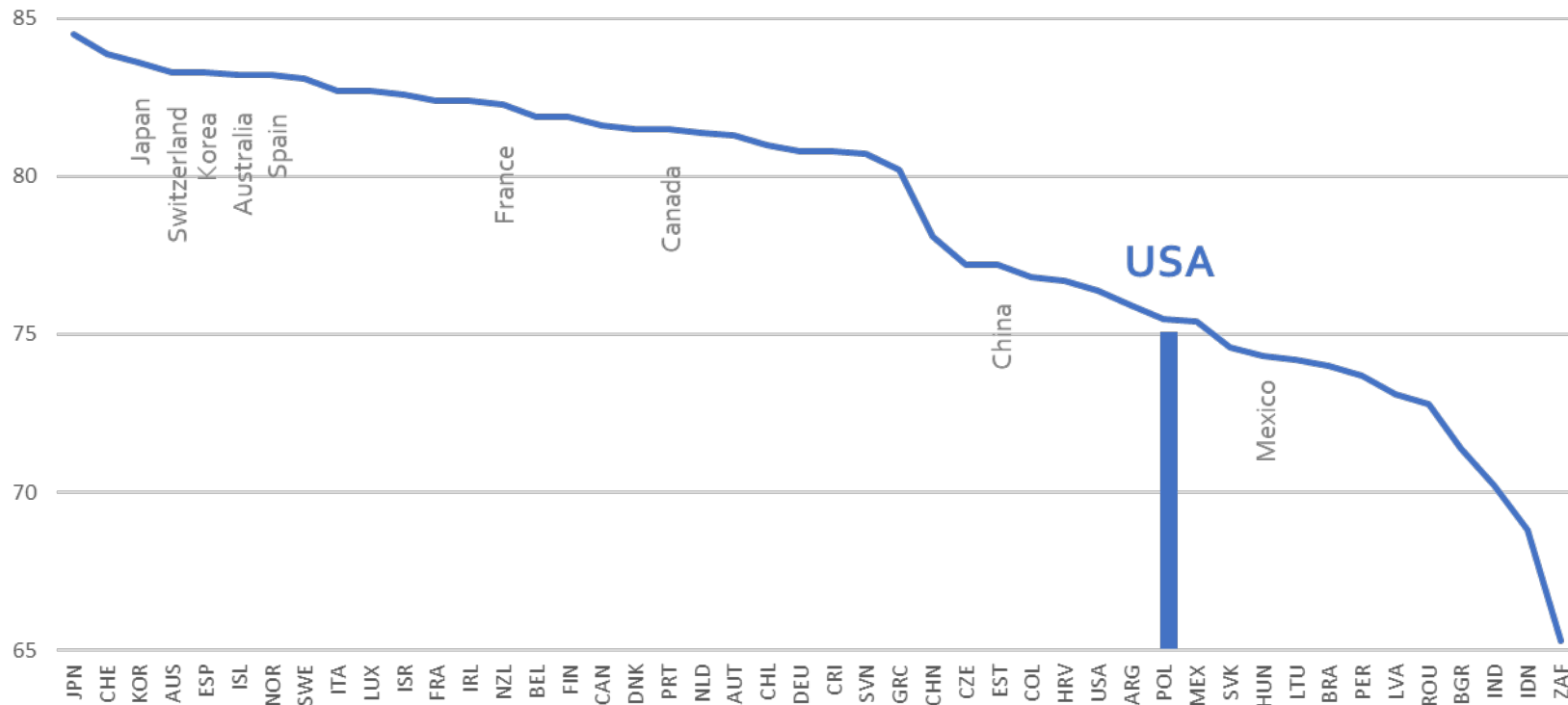
- CARE for Health
- Women's Health Research
- RECOVER
- BRAIN
- Cancer Moonshot
- Childhood and Adolescence
- Alzheimer's

Programs and Initiatives

- **CARE for Health**
- Women's Health Research
- RECOVER
- BRAIN
- Cancer Moonshot
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- Alzheimer's

U.S. life expectancy ranks low among peers

2021 Life Expectancy Throughout World³



Concerning U.S. life expectancy trends:

- Declined 2014-2017¹
- Dropped significantly—2.4 years—between 2019 and 2021²
- Increased in 2022 by 1.1 years; gain does not make up for pandemic losses.²

(1) National Academies of Sciences, Engineering, and Medicine. 2021. *High and Rising Mortality Rates Among Working-Age Adults*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25976>.

(2) Arias E, Kochanek KD, Xu JQ, Tejada-Vera B. Provisional life expectancy estimates for 2022. *Vital Statistics Rapid Release*; no 31. Hyattsville, MD: National Center for Health Statistics. November 2023.

<https://dx.doi.org/10.15620/cdc:133703>.

(3) Chart data: OECD (2024), Life expectancy at birth (indicator). DOI: 10.1787/27e0fc9d-en (Accessed on 10 January 2024)



Our work is not finished when we deliver scientific discoveries, our work is finished when all people are living long and healthy lives.



Communities Advancing Research Equity for Health

CARE for Health™

Integrate
research into
the clinical care
environment

Engender trust in
science by
addressing
community needs

Achieve longitudinal collection of clinical
data to address health across the lifespan

Conduct research addressing
issues important to diverse
communities, particularly
those underrepresented in
biomedical research

Reduce burden on providers
using innovative data
collection methods

Increase
adherence to
evidence-
based care

Improve
efficiency
of care
delivery



Community-based primary care practices

Programs and Initiatives

- CARE for Health
- **Women's Health Research**
- RECOVER
- BRAIN
- Cancer Moonshot
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- Alzheimer's

Expanding women's health research



President Biden's executive order



President Biden's Executive Order To **Advance Research on Women's Health**

As part of the White
House Initiative on
Women's Health
Research

Integrate women's health across the federal research portfolio

Help unlock innovation and open new doors to breakthroughs in women's health

Galvanize research on diseases and conditions associated with women's midlife health

Assess gaps in funding for women's health research

Programs and Initiatives

- CARE for Health
- Women's Health Research
- **RECOVER**
- BRAIN
- Cancer Moonshot
- Childhood and Adolescence
- Alzheimer's

RECOVER by the Numbers

Observational

60 Million
Electronic Health Records

30,000
Enrolled in Clinical Cohorts

60,000
Participants in
Community-based Cohorts

Pathobiology

>40
Studies of Pathogenesis

197
Autopsies Performed

Clinical Trials

>200
Candidate Interventions
Evaluated for Inclusion

8 trials
13 Interventions

5
Adaptive Platform
Master Protocols Across
Multi-therapeutic Domains

Patient and Community Engagement

>1,000
Patients included in Protocol
Design, Trial Application
Review, and/or Symptom
Survey Development

31
Public Seminars on Long
COVID/RECOVER

>500
Diverse and Multi-disciplinary
Investigators and Patients in
RECOVER Consortium

Findings

- **54** Scientific Reports Published/Accepted
- **16** Scientific Reports Under Journal Review
- **77** Scientific Reports In Preparation

Programs and Initiatives

- CARE for Health
- Women's Health Research
- RECOVER
- **BRAIN**
- Cancer Moonshot
- Childhood and Adolescence
- Alzheimer's

The NIH BRAIN Initiative is unique and foundational

- **Innovative** - leveraging synergies and creating new fields of study to enable ground-breaking neuroscience research
- **Inclusive** - building a new generation of scientists and engineers working in new team environments and including people living with brain disorders as partners in research
- **Open** – research for everyone’s benefit
- **Ethical** – understanding what makes us uniquely human, taking stock of both rewards and risks



Programs and Initiatives

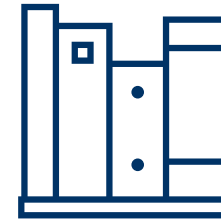
- CARE for Health
- Women's Health Research
- RECOVER
- BRAIN
- **Cancer Moonshot**
- Childhood and Adolescence
- Alzheimer's

CANCER MOONSHOT

PRESIDENT JOE BIDEN

Blue Ribbon Panel Recommendations

1. Establish a network for direct patient involvement
2. Create a translational science network devoted exclusively to immunotherapy
3. Develop ways to overcome cancer's resistance to therapy
4. Build a National Cancer Data Ecosystem
5. Intensify research on the major drivers of childhood cancers
6. Minimize cancer treatment's debilitating side effects
7. Expand use of proven cancer prevention and early detection strategies
8. Mine past patient data to predict future patient outcomes
9. Develop a 3-D cancer atlas
10. Develop new cancer technologies



3,400+
publications



89 clinical trials



78 patent filings

THE PRESIDENT AND FIRST LADY'S

CANCER MOONSHOT

ENDING CANCER AS WE KNOW IT

Goals of the reignited Cancer Moonshot

- Reduce U.S. cancer mortality rate by 50% by 2047
- Improve the experience of people and their families living with and surviving cancer

cancer.gov/moonshot
whitehouse.gov/moonshot

Reignited Cancer Moonshot Activities



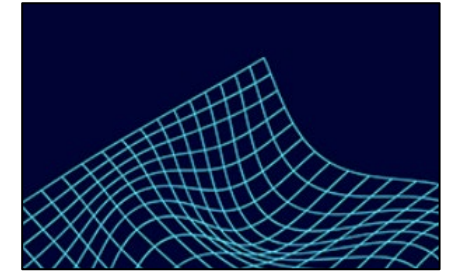
**Cancer Moonshot
Scholars**



**Vanguard Study /
Cancer Screening
Research Network**



**Telehealth Research
Centers of Excellence
(TRACE)**



**ARPA-H Biomedical
Data Fabric Toolbox**



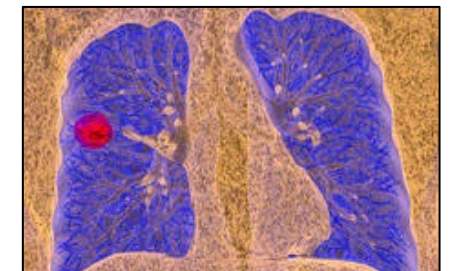
**NAVIGATE
NCI and VA
Interagency Group to
Accelerate Trials
Enrollment**



**NCI + DOE
AI-Driven Multi-Scale
Investigation of the
RAS/RAF Activation
Lifecycle (ADMIRRAL)**



**SmokefreeNATIVE
NCI + IHS**



**HRSA Awards to
Improve Equity in
Cancer Screening**

Childhood and Adolescence



NIH-Supported Scientific Findings on the Impact of Technology and Digital Media in Kids

- **Higher screen time associated with development of mental and behavioral disorders**
 - Adolescent Brain Cognitive Development (ABCD) Study, the largest long-term study of brain development and child health in the U.S.
 - Increased risk of developing disruptive behavior disorders in children aged 9-11 and increased risk of developing OCD and internalizing problems in children aged 9-10
- **Cyberbullying associated with eating disorder symptoms**
 - Data from over 10,000 adolescents enrolled in the ABCD Study
 - 9.5% of participants experienced lifetime cyberbullying, which was associated with worry about weight gain, self-worth tied to weight, inappropriate compensatory behavior, and binge eating
- **Digital autism screening tool may improve early detection**
 - Researcher-developed SenseToKnow app was used to screen 475 toddlers during well-child visits
 - Demonstrated high diagnostic accuracy (87.8% sensitivity and 80.8% specificity)

COVID: Predicting Viral-Associated Inflammatory disease severity in children with Laboratory diagnostics and artificial Intelligence (PreVAIL kids)

- **Develop translational tools to understand the spectrum of pediatric SARS-CoV-2 illness, rapidly diagnose and characterize MIS-C associated with SARS-CoV-2, and predict the longitudinal risk of disease severity** after exposure to and/or infection by SARS-CoV-2
 - Genetics; omics; other biomarkers
 - Viral dynamics and immune profiling studies
 - Digital health platforms leveraged for children
 - Artificial intelligence
- Milestone-driven award (R61/R33); **up to 4 yrs**
- <https://www.nichd.nih.gov/newsroom/news/122120-prevail-kids>



RADxs" Radical (RADx-rad)

RADx-rad will support new, non-traditional approaches, including rapid detection devices and home-based testing technologies, that address current gaps in COVID-19 testing. The program will also support new or non-traditional applications of existing approaches to make them more usable, accessible, or accurate. These may lead to new ways to identify the current SARS-CoV-2 virus as well as potential future viruses.

Budget: \$200 Million

* Note: MIS-C is one of most well-characterized forms of post-acute sequelae of SARS-CoV-2 (PASC) in children

Childhood Injury Prevention: Drowning Prevention Research

- Foremost cause of injury death in children aged 1-4, and a leading cause for children aged 5-19
- Stark racial and socioeconomic disparities in drowning death rates
- Recent study identified disparities in adolescents' access to strategies such as swimming lessons and life jacket use in the same demographic groups who experience higher drowning rates
- NIH released Notice of Special Interest for research on drowning (NOT-HD-21-048). Funded researchers investigating:
 - Virtual reality lifeguard surveillance environment to identify points of failure and inform training tools/strategies
 - Effects of swim instruction on autistic children's swimming and water safety skills
 - Effectiveness of public policy interventions in reducing racial disparities in drowning

Commonly Used Drugs During Lactating and infant Exposure (CUDDLE) Study

- 50-70% of lactating women take prescription drugs though only 2% of common medications have evidence-based recommendations for use in this population
- Extent of transfer into breastmilk is largely unknown
- CUDDLE Study - PK of medicines used during breastfeeding
 - Collects breastmilk, maternal and infant plasma, safety data
 - Opportunistic design → 1600 enrolled; 10 drugs studied
 - Capacity for up to 50 drugs
 - **19 drugs in various stages of enrollment or analysis**
- Drug(s) label changes under review at the FDA for oxycodone, nifedipine, and ondansetron



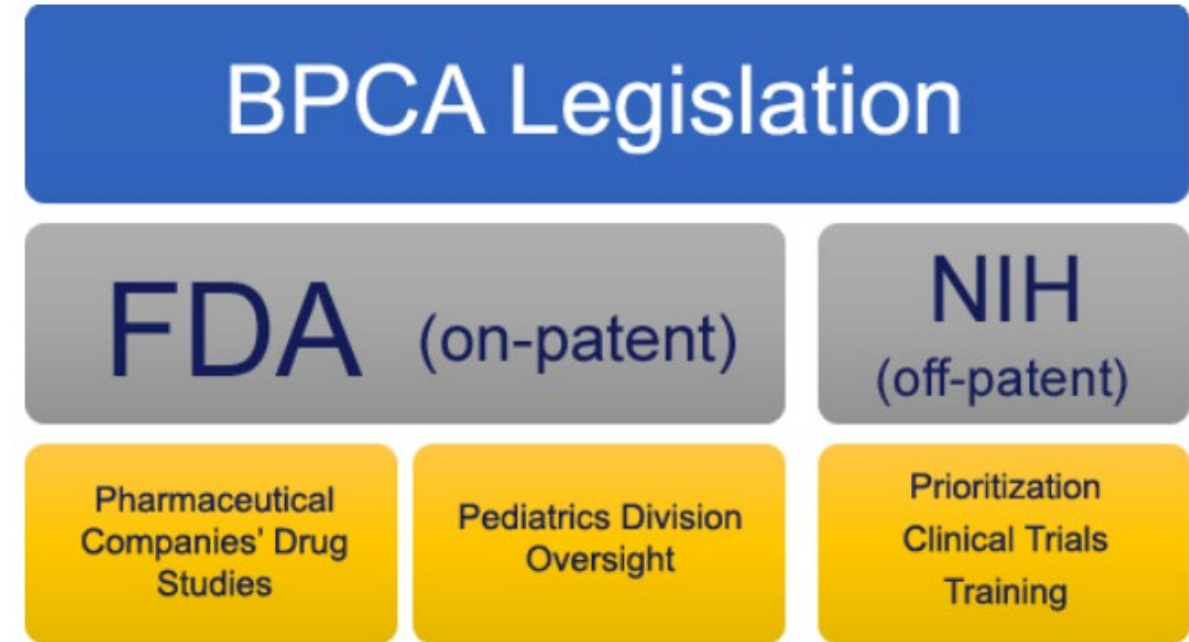
**Drug
taken by
mother**



Pediatric Trials Network

Best Pharmaceuticals for Children Act (BPCA)

- More than 60% of drugs used in children are not labelled or approved for use in pediatric populations
- BPCA became law in 2002; reauthorized in 2007, 2012, 2017 (until 2022)
- Overarching goals of the BPCA for NIH:
 - Identify drugs in need of further study
 - Prioritize needs in pediatric therapeutics
 - Sponsor clinical studies of prioritized drugs



Impact of ABCD Findings on Policy



Journal of Adolescent Health
Volume 69, Issue 3, September 2021, Pages 390-397



Original article

Early Adolescent Substance Use Before and During the COVID-19 Pandemic: A Longitudinal Survey in the ABCD Study Cohort

nature communications

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[nature](#) > [nature communications](#) > [articles](#) > article

Article | [Open access](#) | Published: 02 May 2023

State-level macro-economic factors moderate the association of low income with brain structure and mental health in U.S. children



TAX POLICY CENTER



RESEARCH REPORT

The Return on Investing in Children

Helping Children Thrive

Elaine Maag, Cary Lou, Michelle Casas, Hannah Daly, Gabriella Garriga, and Lillian Hunter
September 2023



Addressing Youth Substance Use through School Services and Supports

Lessons from the District of Columbia, Massachusetts, and New Mexico

nature

Article | [Open access](#) | [Published: 06 April 2022](#)

Brain charts for the human lifespan



Optimizing brain health across the life course:

WHO position paper

A microscopic image of neurons, showing their complex branching structures. The neurons are highlighted in a bright yellow-gold color against a dark blue background. The text "Progress in Alzheimer's and Related Dementias Research" is overlaid in white, bold font in the center of the image.

Progress in Alzheimer's and Related Dementias Research

AD/ADRD research across the research spectrum



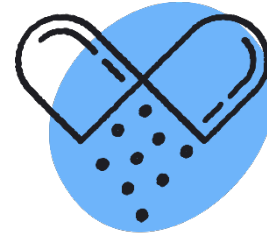
Basic Science

Understanding the biological mechanisms and processes that contribute to health and disease



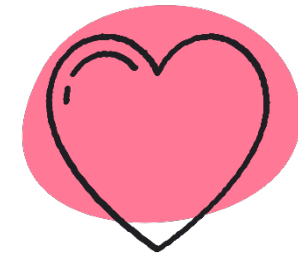
Risk Reduction

Identifying ways to reduce the risk of developing AD/ADRD



Clinical Trials and Drug development

Testing the safety and efficacy of potential new treatments



Care and Caregiving

Establishing clinical care strategies, long-term supports and services, and approaches to caregiver support

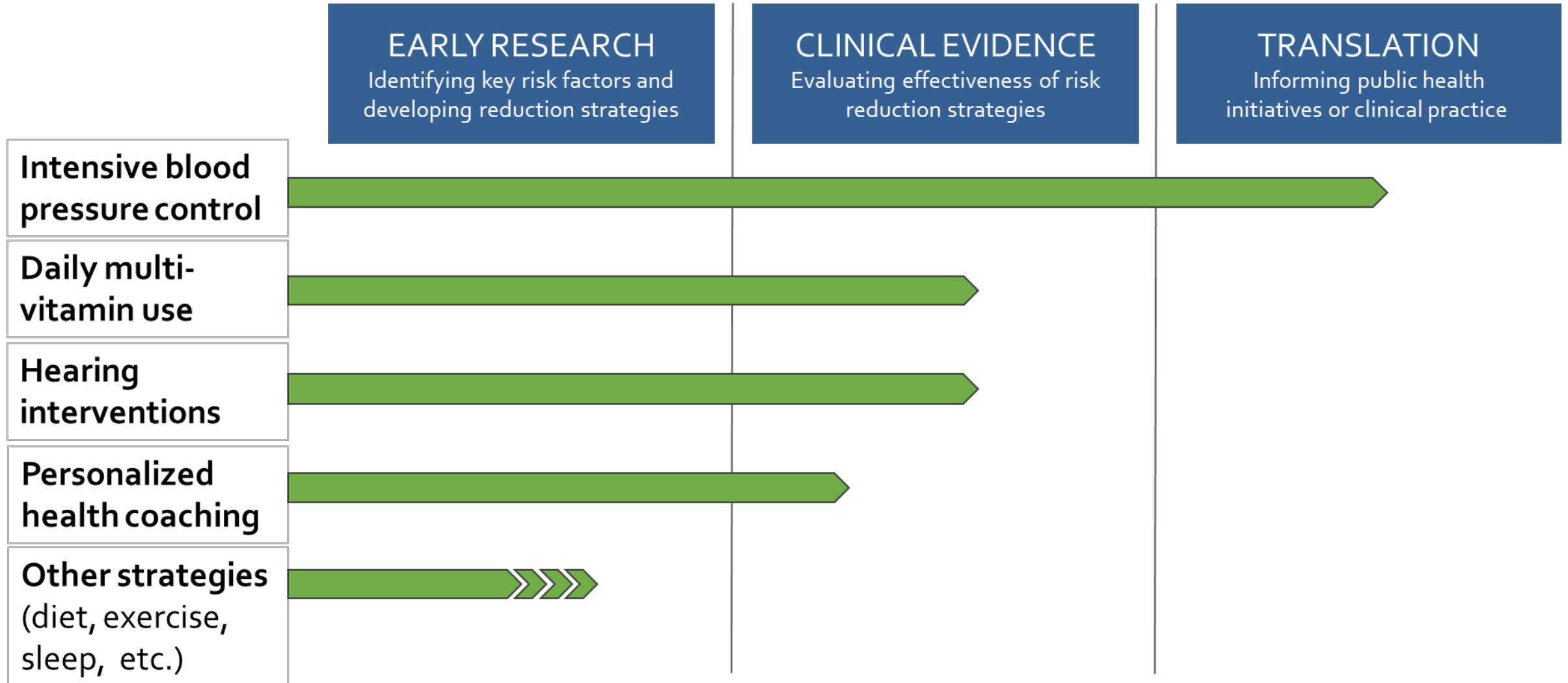
Recent Progress in Alzheimer's Disease

Tools	2016	2023
Diagnostics	<ul style="list-style-type: none">• Amyloid PET agents	<ul style="list-style-type: none">• Amyloid PET agents• Tau PET agents (e.g., flortaucipir)• Blood biomarkers for amyloid and tau (e.g., PrecivityAD/PrecivityAD2)• Data-based tools (e.g., eRADAR)• Electronic/digital assessments
Symptom Management	<ul style="list-style-type: none">• Cholinesterase inhibitors (e.g., donepezil)• Glutamate regulators (e.g., memantine)	<ul style="list-style-type: none">• Cholinesterase inhibitors (e.g., donepezil)• Glutamate regulators (e.g., memantine)• Brexpiprazole for agitation related to AD (approved 2023)• Interventions for care and caregivers

Recent Progress in Alzheimer's Disease

Tools	2016	2023
Disease-Modifying Therapies	None	<ul style="list-style-type: none">• Lecanemab (FDA approval in 2023)• Donanemab (Under FDA consideration)• Many additional therapies in the pipeline, with more diverse targets than ever before
Risk Reduction	None	<ul style="list-style-type: none">• Intensive blood pressure control• Hearing interventions• Daily multivitamin use• Personalized lifestyle interventions
Care & Caregiving	Foundational work to develop and test specific care models for efficacy & effectiveness	<ul style="list-style-type: none">• Two intervention types in process of implementation with continued evaluation: REACH II and The Collaborative Care Model• Multiple lines of study on adaptations and broader implementation of promising models

Multiple Emerging Strategies for Risk Reduction





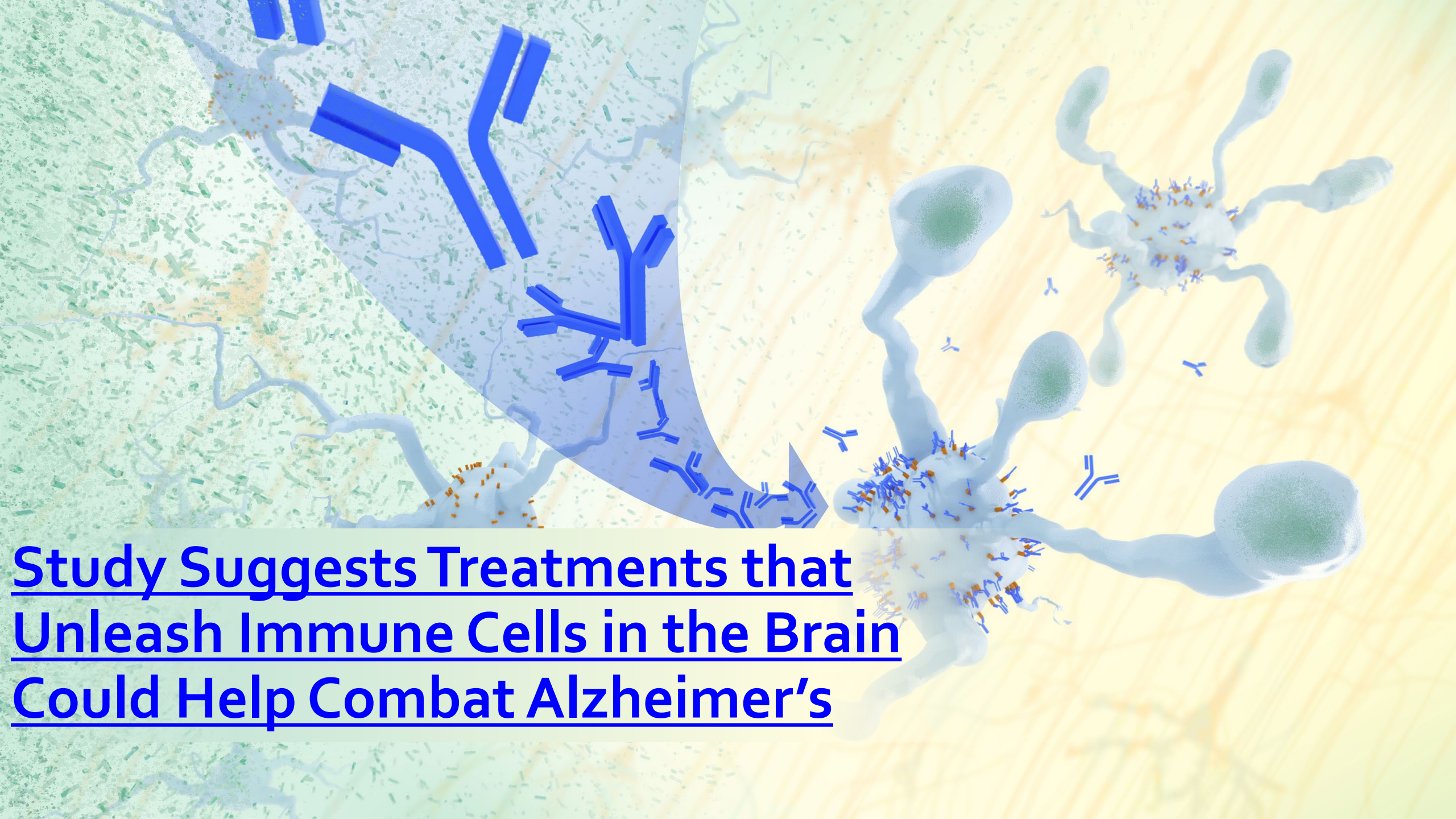
Science Highlights

Speeding the Diagnosis of Rare Genetic Disorders with the Help of Artificial Intelligence




Understanding Childbirth Through a Single-Cell Atlas of the Placenta

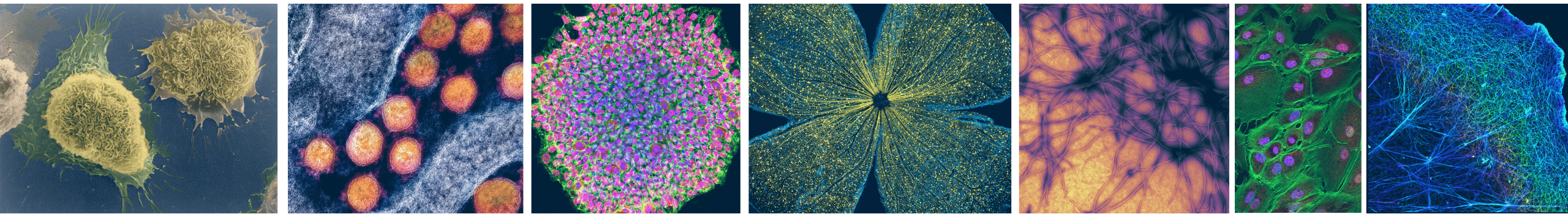




Study Suggests Treatments that Unleash Immune Cells in the Brain Could Help Combat Alzheimer's



Most Detailed 3D
Reconstruction of Human
Brain Tissue Reconstructed
with AI Models



NIH

Turning Discovery Into Health

