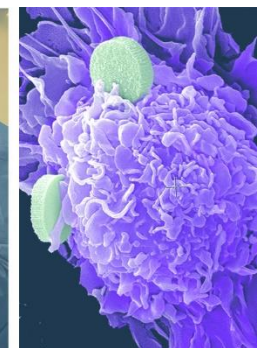
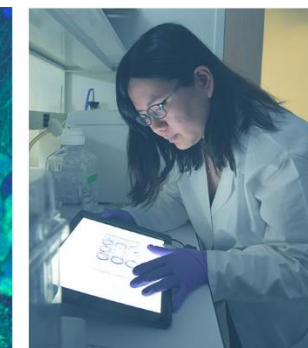
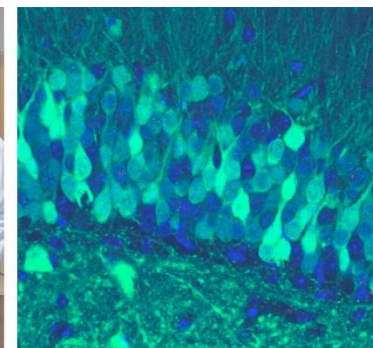
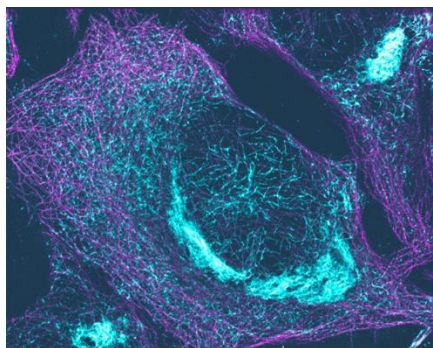
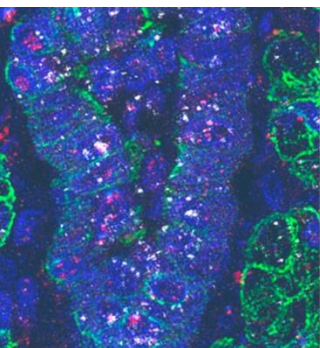


# Director's Report

128<sup>th</sup> 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**



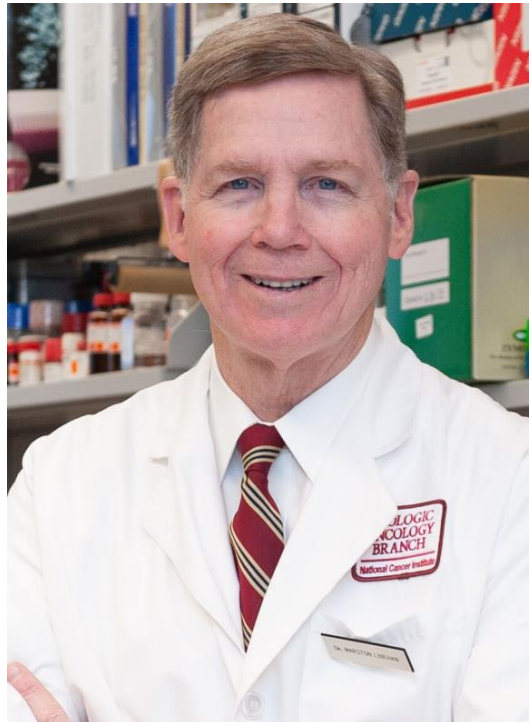
**Camille Hoover, MSW  
NIDDK**



**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









# 10<sup>th</sup> 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 RESEARCH



Valerie Montgomery Rice  
Emory School of Medicine

First Lady Jill Biden

Ms. Maria Toler  
Emory School of Medicine

WHITE HOUSE INITIATIVE







# Vint Cerf Rall 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	<b>\$28,224 (4%)</b> Predocs	<b>\$61,008 (8%)</b> Postdocs	
FY24 Benefits	<b>\$4,750</b> Predoc TRE/IA	<b>\$12,400</b> Postdoc TRE/IA	<b>\$3,000</b> 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.**

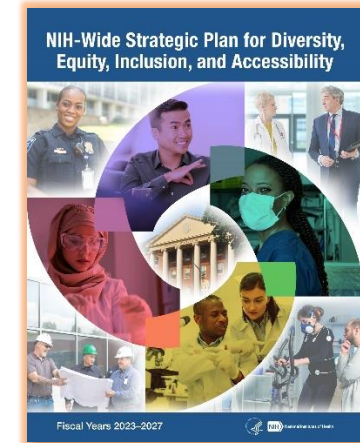


# Updating the Mission Statement: Request for Information (RFI)

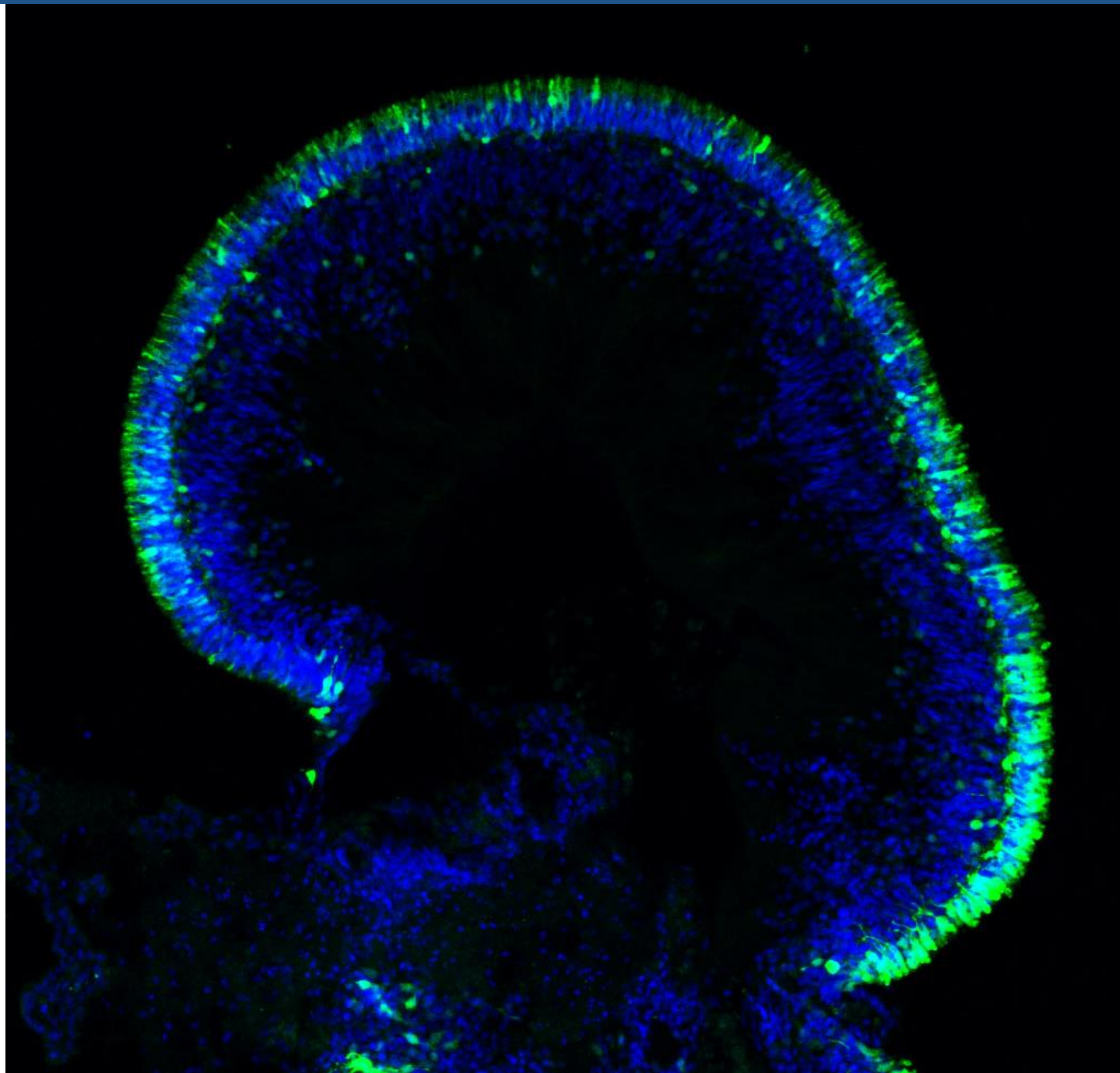
- Released RFI to gather internal and external input
- Received 480 total responses
  - Public report on RFI will be posted in coming weeks
- Strong, opposing views expressed in RFI
  - 40%: add “disability” back into the statement in some way
    - Develop an alternative way to include disability
    - 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



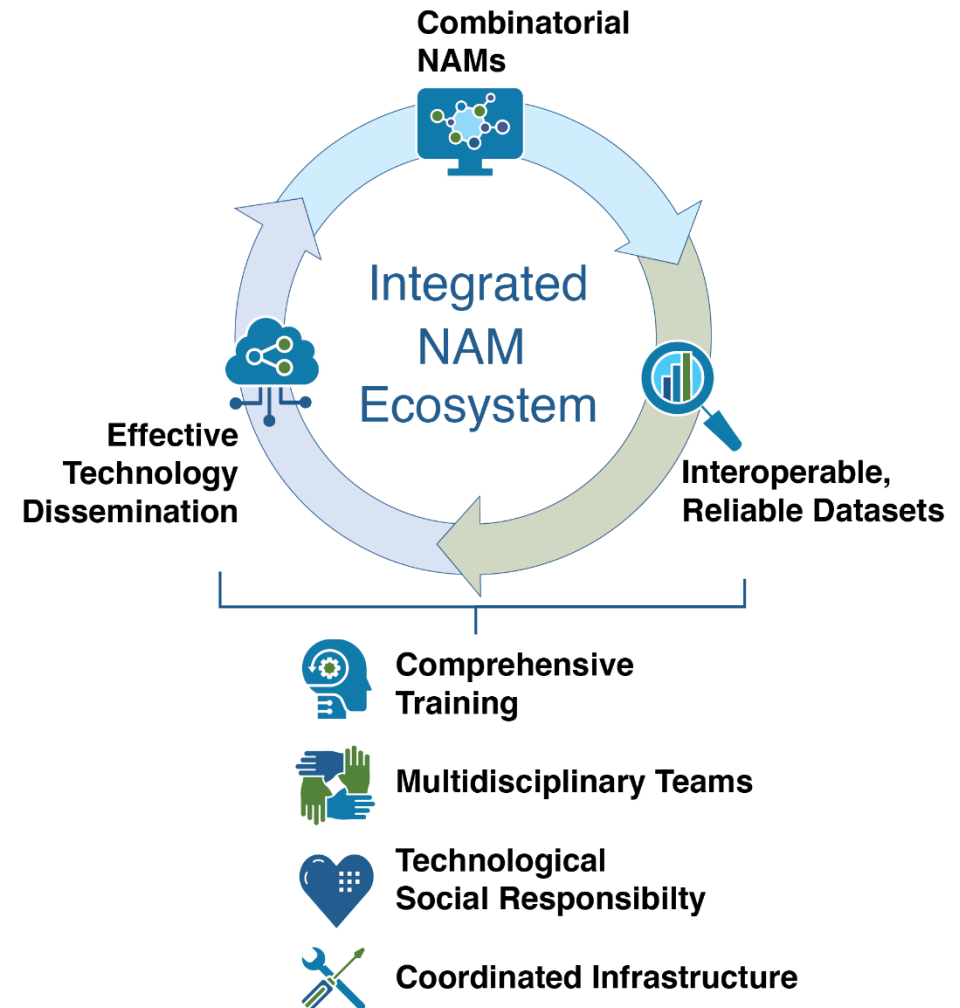
# Novel Alternative Methods





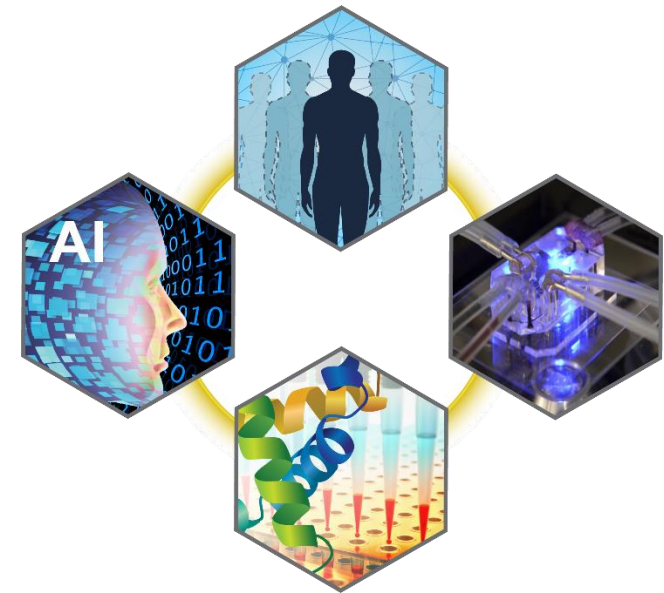
# Catalyzing the Development and Use of New Approach Methods (NAMs)

- 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

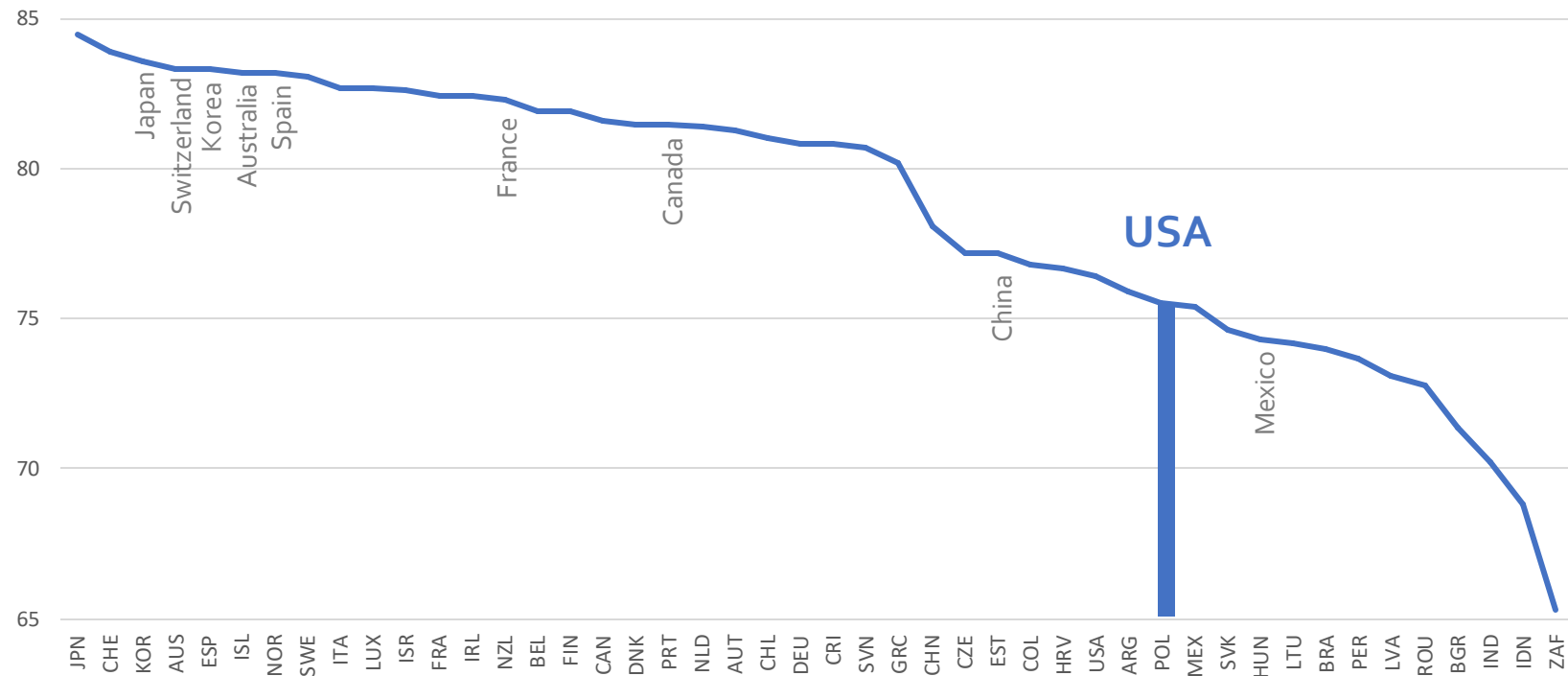


# Programs and Initiatives

- CARE for Health
- Women's Health Research
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- Alzheimer's

# U.S. life expectancy ranks low among peers

2021 Life Expectancy Throughout World<sup>3</sup>



## Concerning U.S. life expectancy trends:

- Declined 2014-2017<sup>1</sup>
- Dropped significantly—2.4 years—between 2019 and 2021<sup>2</sup>
- Increased in 2022 by 1.1 years; gain does not make up for pandemic losses.<sup>2</sup>

(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
- Childhood and Adolescence
- Alzheimer's



# Expanding women's health research







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

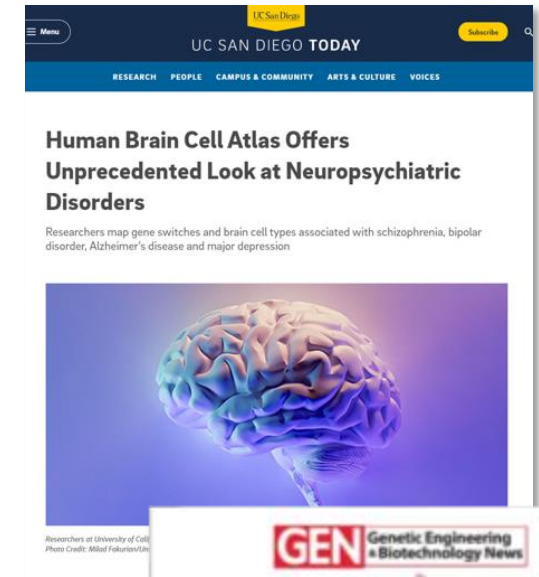


# Programs and Initiatives

- 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

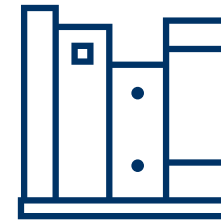


# CANCER MOONSHOT

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

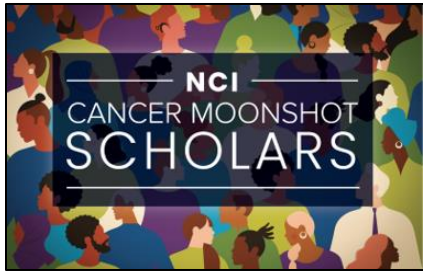
ENDING CANCER AS WE KNOW IT

## 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](https://cancer.gov/moonshot)  
[whitehouse.gov/moonshot](https://whitehouse.gov/moonshot)*

# Reignited Cancer Moonshot Activities



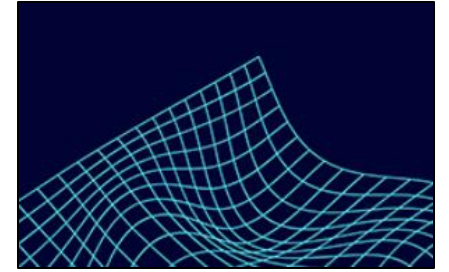
**Cancer Moonshot  
Scholars**



**Vanguard Study /  
Cancer Screening  
Research Network**



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



**ARPA-H Biomedical  
Data Fabric Toolbox**



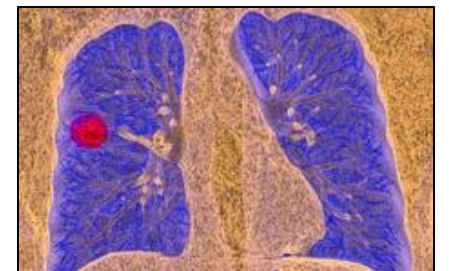
**NAVIGATE  
NCI and VA  
Interagency Group to  
Accelerate Trials  
Enrollment**



**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>



## **RADx<sup>SM</sup> 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



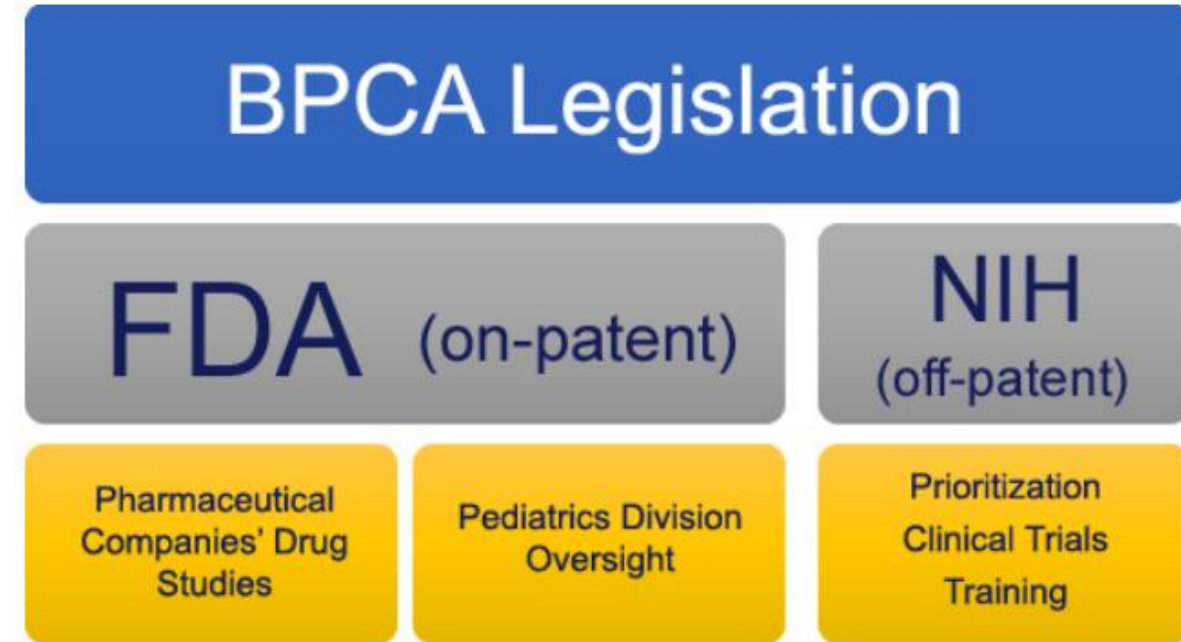
Drug  
taken by  
mother



# 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 central text is overlaid on the image.

# Progress in Alzheimer's and Related Dementias Research



# AD/ADRD research across the research spectrum



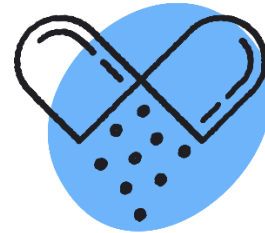
## **Basic Science**

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



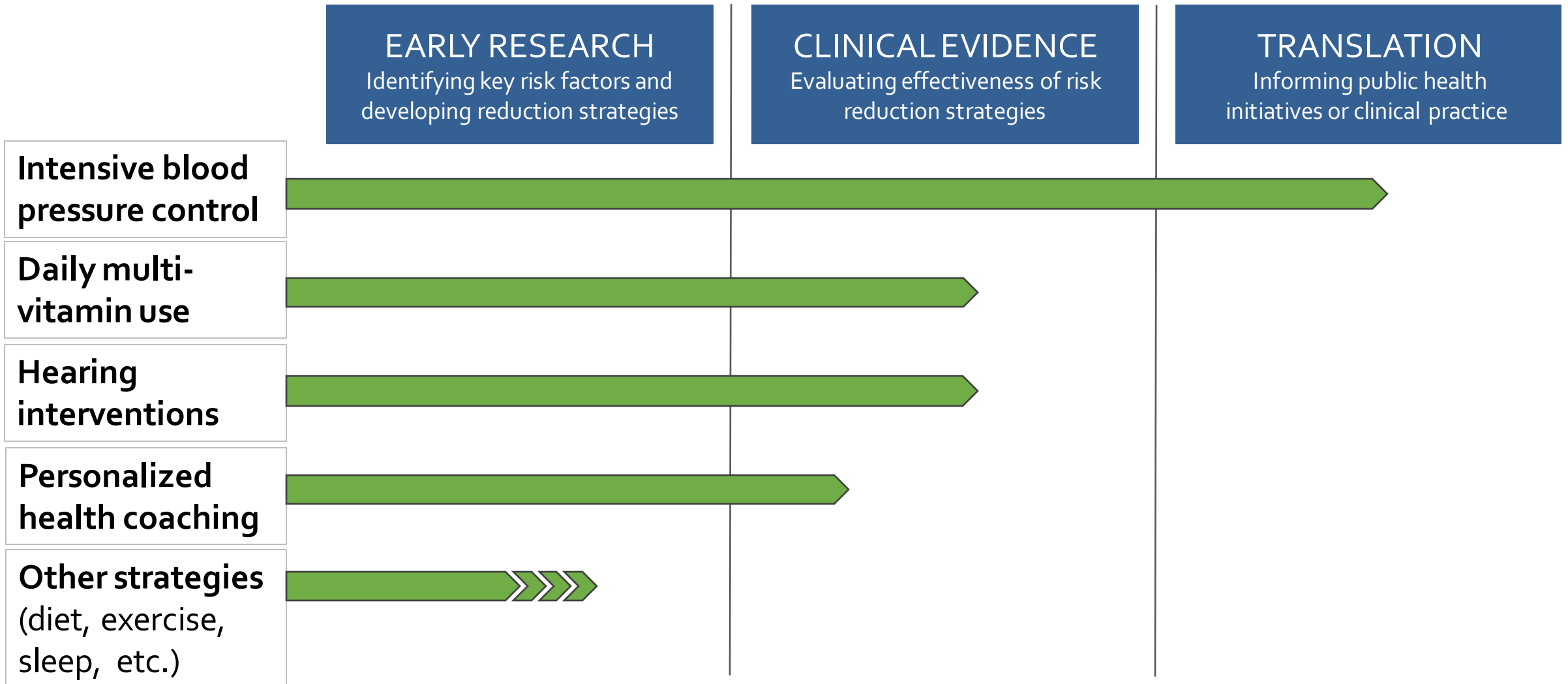
# Recent Progress in Alzheimer's Disease

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

# Recent Progress in Alzheimer's Disease

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

# Multiple Emerging Strategies for Risk Reduction

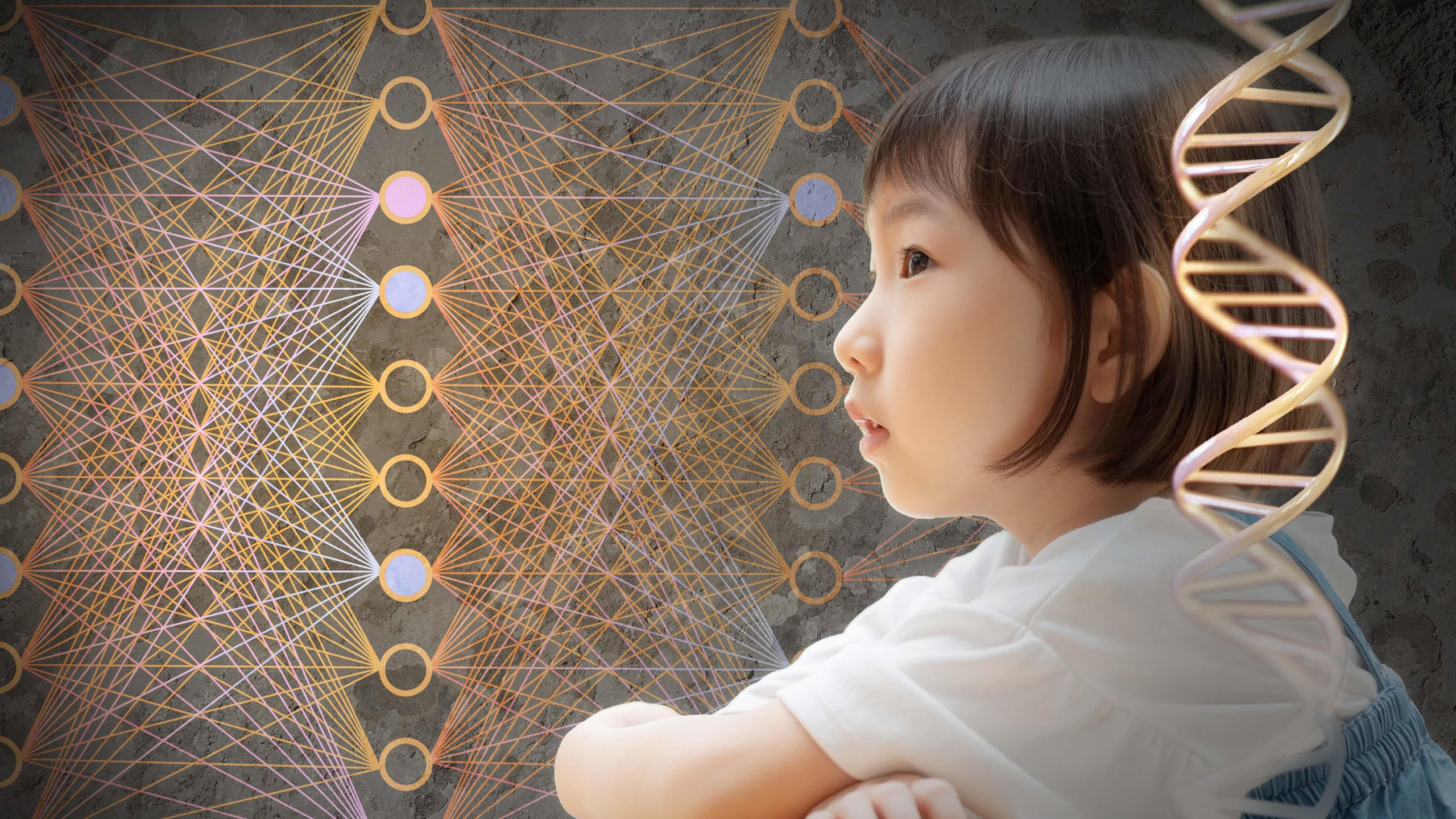






# Science Highlights

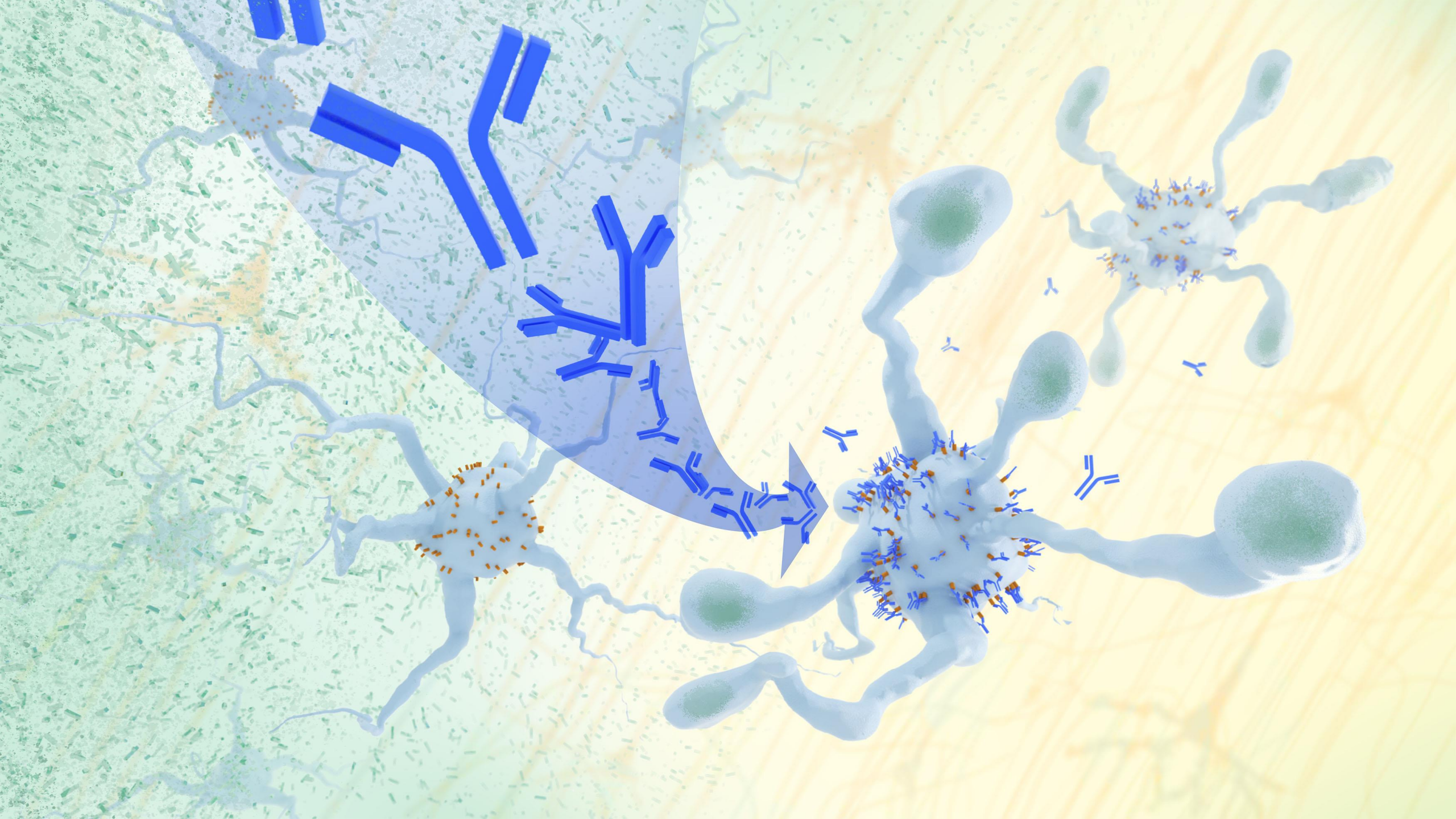




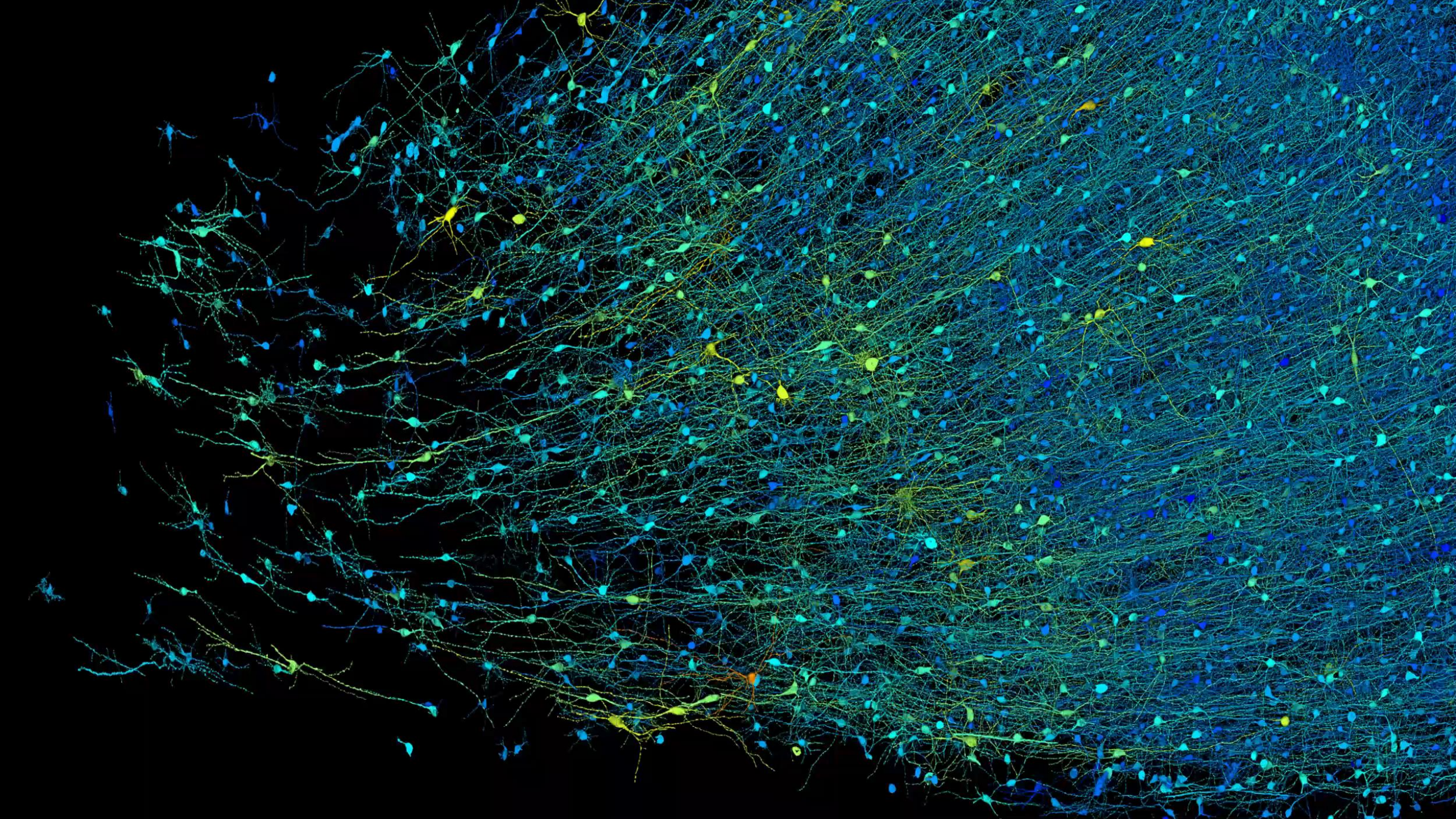




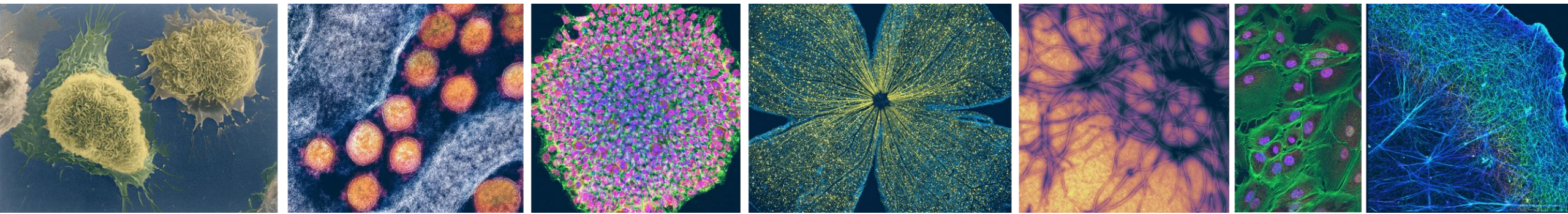












# NIH

*Turning Discovery Into Health*

