Director's Report

127th Advisory Committee to the Director Meeting
December 14, 2023
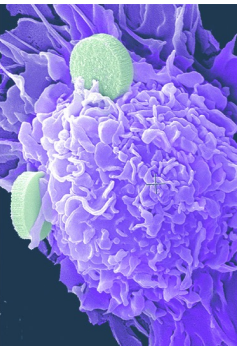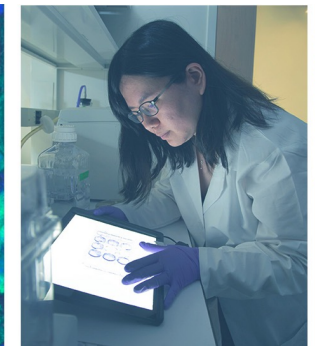
Monica M. Bertagnolli, MD
Director, National Institutes of Health
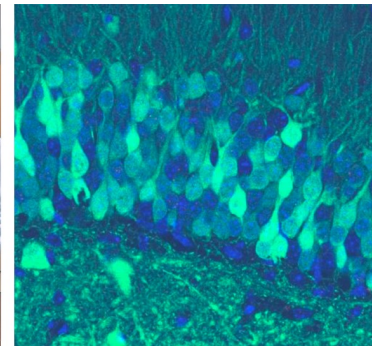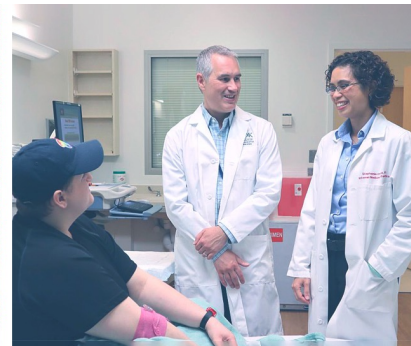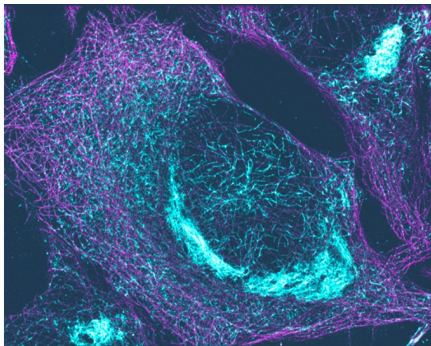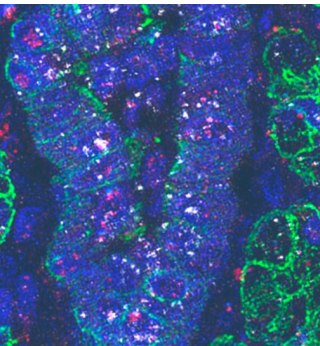
Our job at NIH is not done when scientific discoveries are made.

Our job is done when people are living long and healthy lives.

Pew Research Center

Americans' Trust in Scientists, Positive Views of Science Continue to Decline
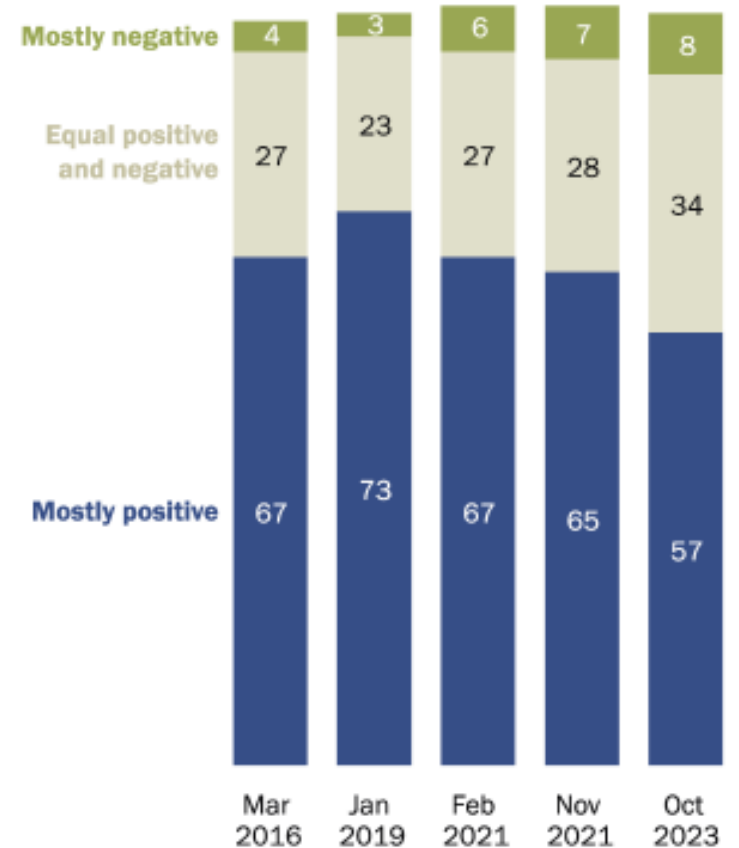
Among both Democrats and Republicans, trust in scientists is lower than before the pandemic

Why does public trust in science matter?

- People who trust scientists are more likely to follow expert guidance, such as get vaccines for COVID-19 and the flu
- Differences in levels of trust among groups (based on political beliefs, race & ethnicity, education) could mean uneven spread of the benefits of science across society

Fewer Americans now say science has had a mostly positive effect on society

% of U.S. adults who say science has had a(n) ___ effect on society

	Mar 2016	Jan 2019	Feb 2021	Nov 2021	Oct 2023
Mostly negative	4	3	6	7	8
Equal positive and negative	27	23	27	28	34
Mostly positive	67	73	67	65	57

Note: Respondents who did not give an answer are not shown.
Source: Survey of U.S. adults conducted Sept. 25-Oct. 1, 2023.
"Americans' Trust in Scientists, Positive Views of Science Continue to Decline"

PEW RESEARCH CENTER

Topics for Today

- NIH Leadership Changes
- Awards
- Events
- Supporting individuals with disabilities in the biomedical research workforce
- Simplified Review Criteria
- AI at NIH
- Programs and Initiatives
  - ComPASS awards
  - Cancer Moonshot
  - HEAL
  - RECOVER
  - Accelerating Medicines Partnership (AMP)
- Science Highlights:
  - Brain atlas

NIH Leadership Changes

NIH Deputy Director for Program Coordination, Planning, and Strategic Initiatives

Tara A. Schwetz, PhD

Director, National Institute of Allergy and Infectious Diseases

Jeanne M. Marrazzo, MD, MPH

Director, National Cancer Institute

Kimryn Rathmell, MD, PhD

Retirement:
Director, National Library of Medicine

Patricia Flatley Brennan, RN, PhD

Acting Director, National Library of Medicine

Stephen Sherry, PhD

NIH Associate Director for Legislative Policy and Analysis

Kate Klimczak

NIH Associate Director for Science Policy

Lyric Jorgenson, PhD

NIH Associate Director for Behavioral and Social Sciences Research

Jane M. Simoni, PhD

Director, Office of Nutrition Research

Andrew A. Bremer MD, PhD

Chief of Staff, NIH Office of the Director

John T. Burklow

Awards

National Medal of Technology and Innovation

Steven Rosenberg, MD, PhD

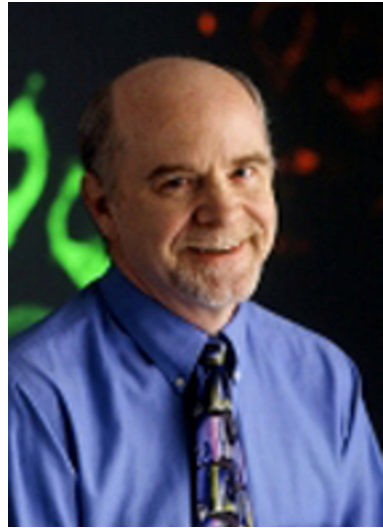# 2023 Nobel Prize in Physiology or Medicine

NIH grantees Dr. Katalin Karikó and Dr. Drew Weissman

Elected to National Academy of Sciences

Elected to National Academy of Medicine

Andre Nussenzweig, PhD

John O'Shea, MD

Michael F. Chiang , MD

Eric Green, MD, PhD

Events

Supporting individuals with disabilities in the biomedical research workforce

Updating Our Mission Statement

Current statement:

NIH's mission is 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 revision:

NIH's mission is 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.

RFI Inviting Public Comment on Mission Statement

NOT-OD-23-163: Request for Information (RFI):
Inviting Comments and Suggestions on Updating the NIH Mission Statement

Closed November 24 -- Analysis of the responses is ongoing

Designating people with disabilities as a population with health disparities

- Announced Sept. 26, 2023

- NIMHD issued a funding opportunity for research on approaches and interventions to address the intersections of disability, race, ethnicity and socioeconomic status on health care access and outcomes.

Disabilities Subgroup of the Steering Committee DEIA Working Group

Culture

Ableism

Research policies & systems

Simplified Review Criteria

Simplified Review Criteria for NIH Grants

For due dates before Jan 25, 2025

All considered in overall impact score

- **Significance** - scored
- **Investigator(s)** - scored
- **Innovation** - scored
- **Approach** - scored
- **Environment** - scored

For due dates on/after Jan 25, 2025

- **Factor 1: Importance of Research**
  - Criteria: Significance, Innovation
  - Scored 1-9
- **Factor 2: Rigor and Feasibility**
  - Criterion: Approach (also includes Inclusions and Clinical Trial Study Timeline)
  - Scored 1 - 9
- **Factor 3: Expertise and Resources**
  - Criteria: Investigators, Environment
  - Evaluated as appropriate or gaps identified; gaps require explanation
  - Considered in overall impact, no individual score

Next steps between now and January 2025

- **Fall 2023:**
  - ✓ Issue Guide Notice announcing changes
  - ✓ Staff webinar: overview of changes and timeline for implementation
  - ✓ Public webinar: overview of changes – **November 3** (recording posted)
- **Over the next year:**
  - o Additional public webinars
  - o Changes to NIH systems
  - o Developing training resources
  - o Updating and publishing funding opportunities

One-stop shop, central NIH site with information, FAQs:

https://grants.nih.gov/policy/peer/simplifying-review.htm

A wealth of outreach to socialize the change for reviewers, chairs, applicants, staff

AI @ NIH

Challenges

- Lack of clinical and healthcare data, with careful annotations, that are representative of the full diversity of the American people

- Lack of data in lived experiences, historical/cultural contexts such as social determinants of health (SDOH)

- Need for validated, ethical and trustworthy AI algorithms in health settings

- Lack of diversity in AI workforce and challenges in disseminating AI technologies to diverse populations

Bridge2AI

Goals

- Generate AI/ML-ready, flagship datasets
- Develop best practices for implementing ethical principles for AI data sets and models
- Train AI/ML scientists for biomedical research

4 grand challenge Data Generation Projects (DGPs):

- Clinical Care (Model ICU data)
- Precision Public Health (Voice as a Biomarker)
- Salutogenesis
- Functional Genomics

Jamboree

Planned for Spring 2024 for AI/ML experts to interact with pilot data

Community Engagement

- Established a public portal
- Started webinar training series
- Hosted workshops/symposia
- Launched year-long internship

Data Generation

- Started pilot data collection for flagship data sets
- Functional Genomics Multi-Scale Integrated (MuSIC) toolkit

AIM-AHEAD supports diverse researchers and projects

- Nationwide consortium with 24 hubs
- 29 lead investigators, > 50 researchers, > 1,500 students and trainees

- Partnerships with communities
- Research at the intersection of AI and health disparities
- Training
- Infrastructure enhancements

Additional AI Projects Across NIH

- Common Fund: **Nutrition** for Precision Health (NPH)

- NIMHD: Science collaborative for **health disparities** and AI **bias** reduction (ScHARe)

- NIA: Center for **Alzheimer's** and **Related Dementias** (CARD) and AI and Technology Collaboratories (AITC) for **Aging** Research

- NIDA: ML **opioid** prediction and risk stratification e-platform

- NCI & DOE: Advanced computing and AI for **cancer** research

- NIMH: AI for decoding and modulating **neural** circuit activity linked to **behavior**

Programs and Initiatives

Community Partnerships to Advance Science for Society (ComPASS) Program
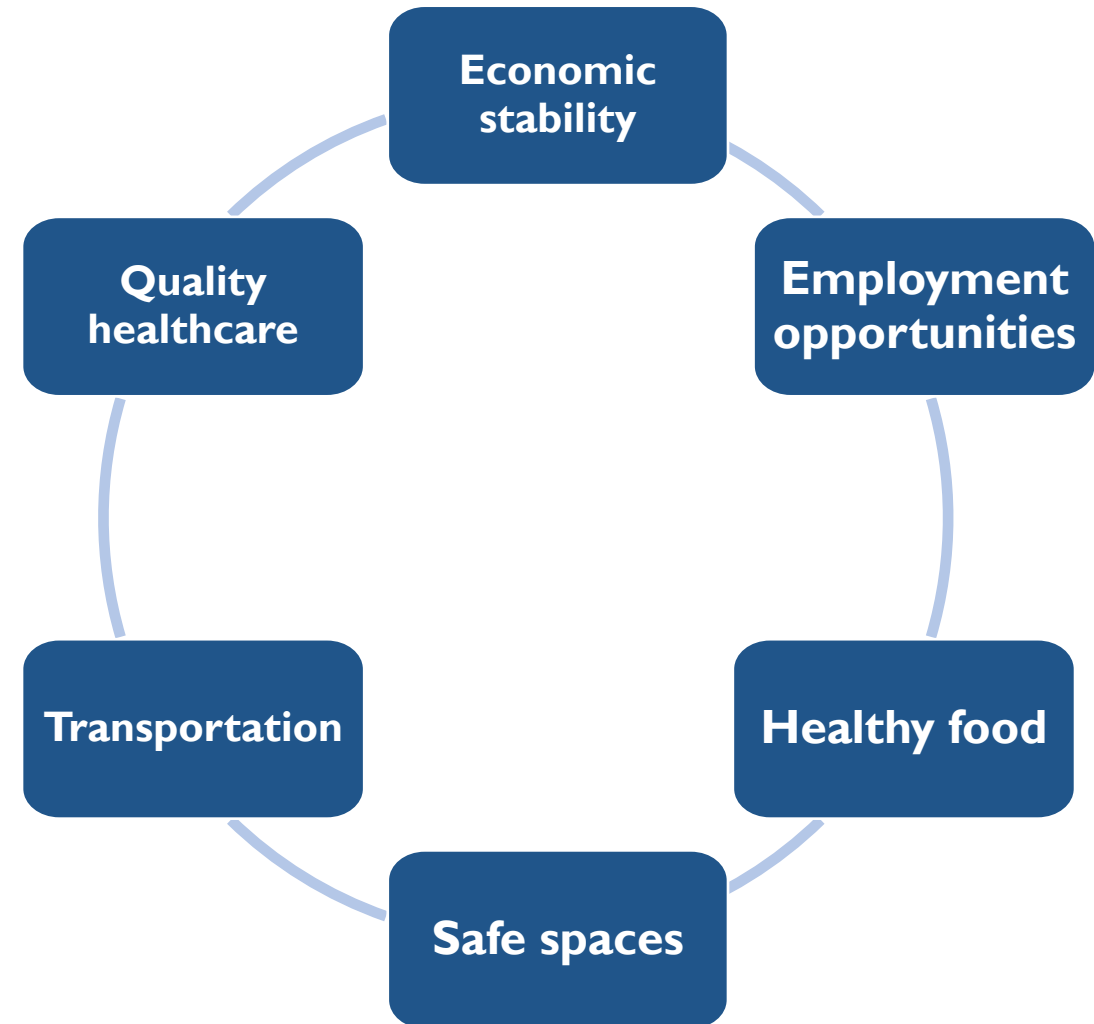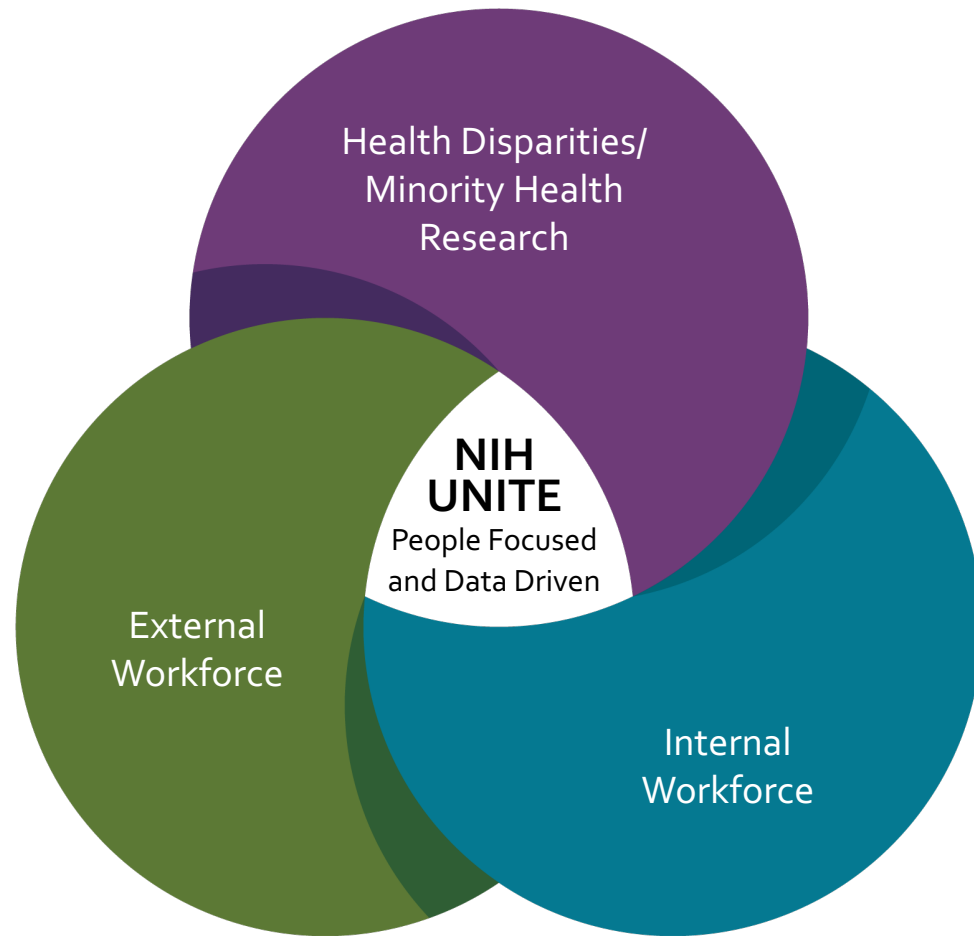
ComPASS Initiatives

Community-Led, Health Equity Structural Interventions
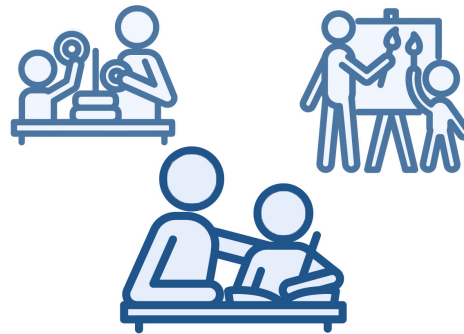
Health Equity Research Hubs

ComPASS Coordination Center

ComPASS: Projects Funded

Access to healthy food in underserved rural communities

Early childcare strategies and mental health

Enhancing telehealth models in rural communities

Cancer Moonshot

- Reduce U.S. cancer death rate by 50% in the next 25 years (by 2047)

- Improve the lives of people and their families living with and surviving cancer

National Cancer Plan

A plan for the National Cancer Program to align broad societal engagement and focus on critical needs to end cancer as we know it.

GOALS:

- **Prevent Cancer**

- **Detect Cancers Early**

- **Develop Effective Treatments**

- **Eliminate Inequities**

- **Deliver Optimal Care**

- **Engage Every Person**

- **Maximize Data Utility**
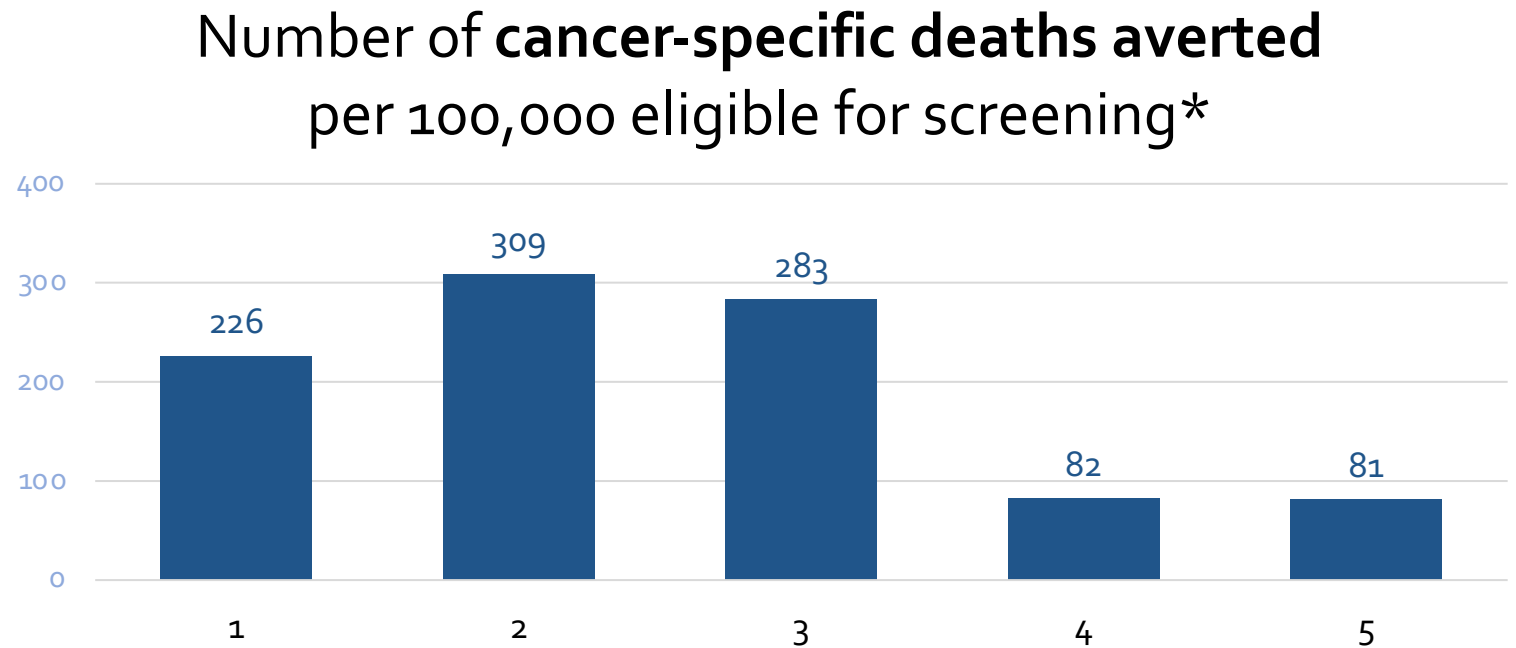
- **Optimize the Workforce**

National Cancer Plan Initial Stakeholder Meeting – Sept. 7, 2023

- Common themes and priority areas:
  - Recruiting and retaining a diverse cancer research and care **workforce**
  - Providing **accessible care** regardless of a patient's geographic location or insurance status
  - **Data sharing** and interoperability
  - Integrating **social determinants of health** into research and the cancer care continuum

PRESIDENT'S CANCER PANEL

Working Toward the Moonshot Cancer Mortality Reduction Goal

- A new NCI-supported analysis shows increasing uptake of recommended screening strategies could reduce cancer burden in U.S.

- The numbers are estimated based on a 10–percentage point increase in the use of US Preventive Services Task Force-recommended screening

Number of **cancer-specific deaths averted** per 100,000 eligible for screening*

Category	Deaths averted
1	226
2	309
3	283
4	82
5	81

How to Increase Cancer Screening: Address Social Determinants of Health

Recent review of cancer screening intervention studies:

Social determinants of health interventions increased cancer screening rates (breast, cervical, colorectal, lung) by 8.4 percentage points.

Education Access & Quality

Health Care Access and Quality

Economic Stability

Neighborhood and Built Environment

Social and Community Context

How to Increase Cancer Screening: Multi-Cancer Detection Blood Tests

The Cancer Screening Research Network (CSRN), funded in part by the Cancer Moonshot, will conducts trial and studies specifically related to cancer screening.

Vanguard Study on Multi-Cancer Detection:

- Evaluate the effectiveness of new blood tests to detect one or more cancer(s) to prevent cancer-related deaths
- *Seven centers will be funded (anticipate announcing in January 2024)*

NIH Helping to End Addiction Long-term® Initiative (NIH HEAL Initiative®)
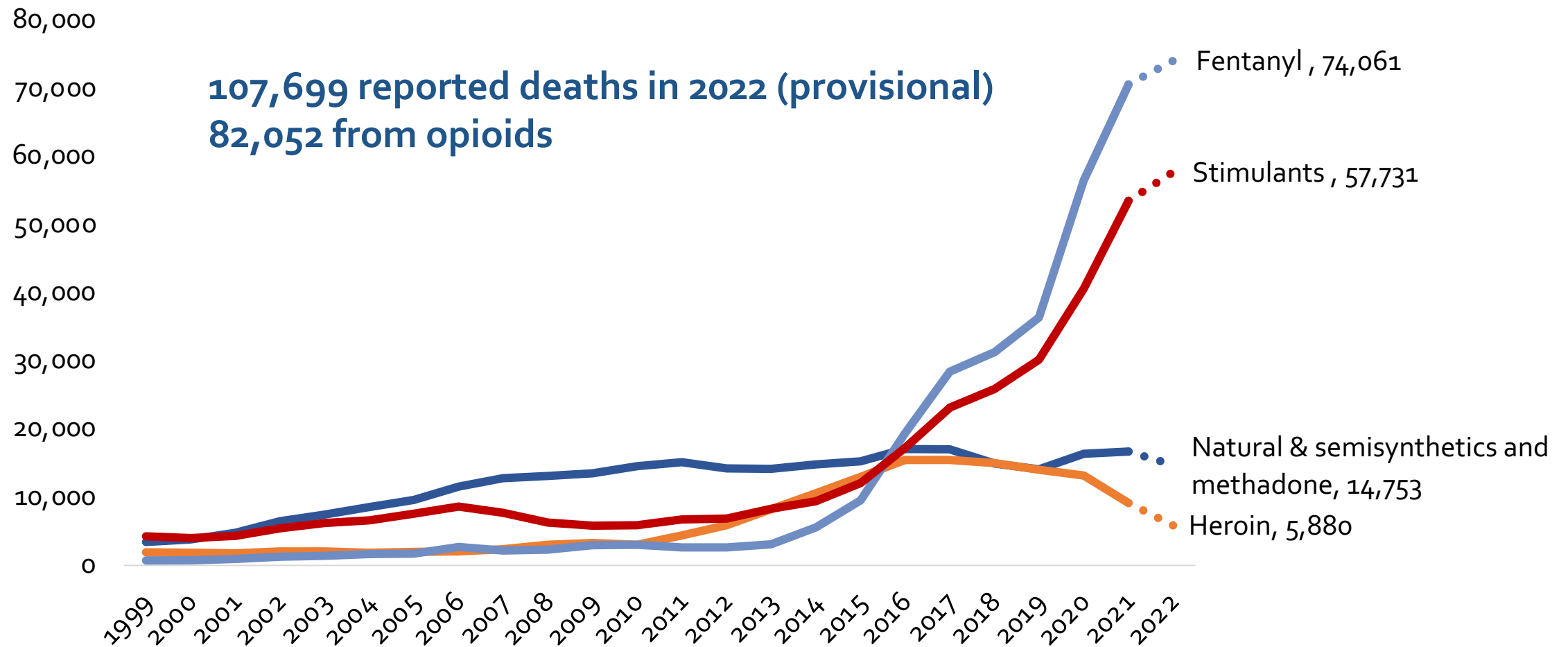
- Launched in 2018
- Goal: Find scientific solutions to the opioid public health crisis

Image credit: Zoran Zeremski/Shutterstock
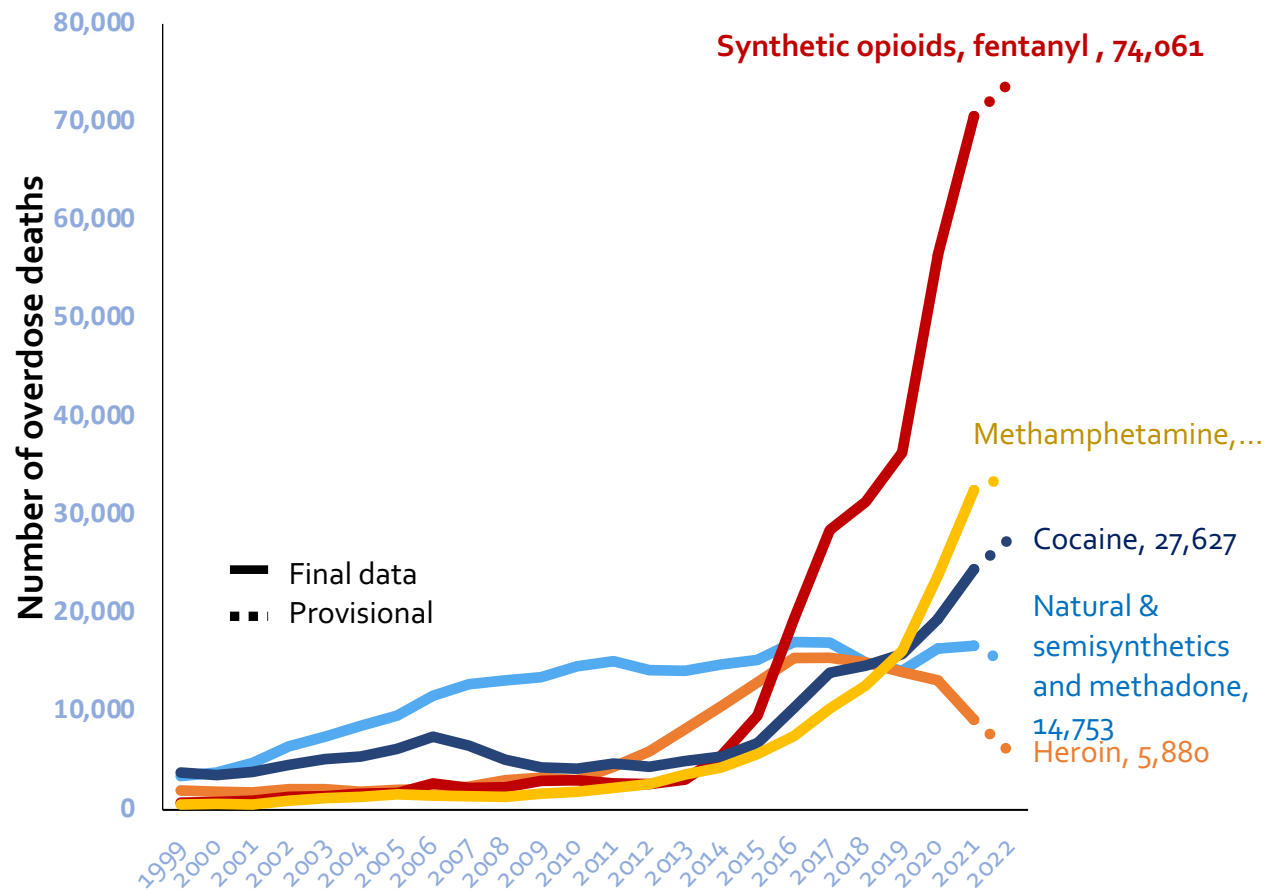
Evolution of Drivers of Overdose Deaths, All Ages

Analgesics ➡ Heroin ➡ Fentanyl ➡ Stimulants

**107,699 reported deaths in 2022 (provisional)
82,052 from opioids**

Fentanyl , 74,061

Stimulants , 57,731

Natural & semisynthetics and methadone, 14,753

Heroin, 5,880

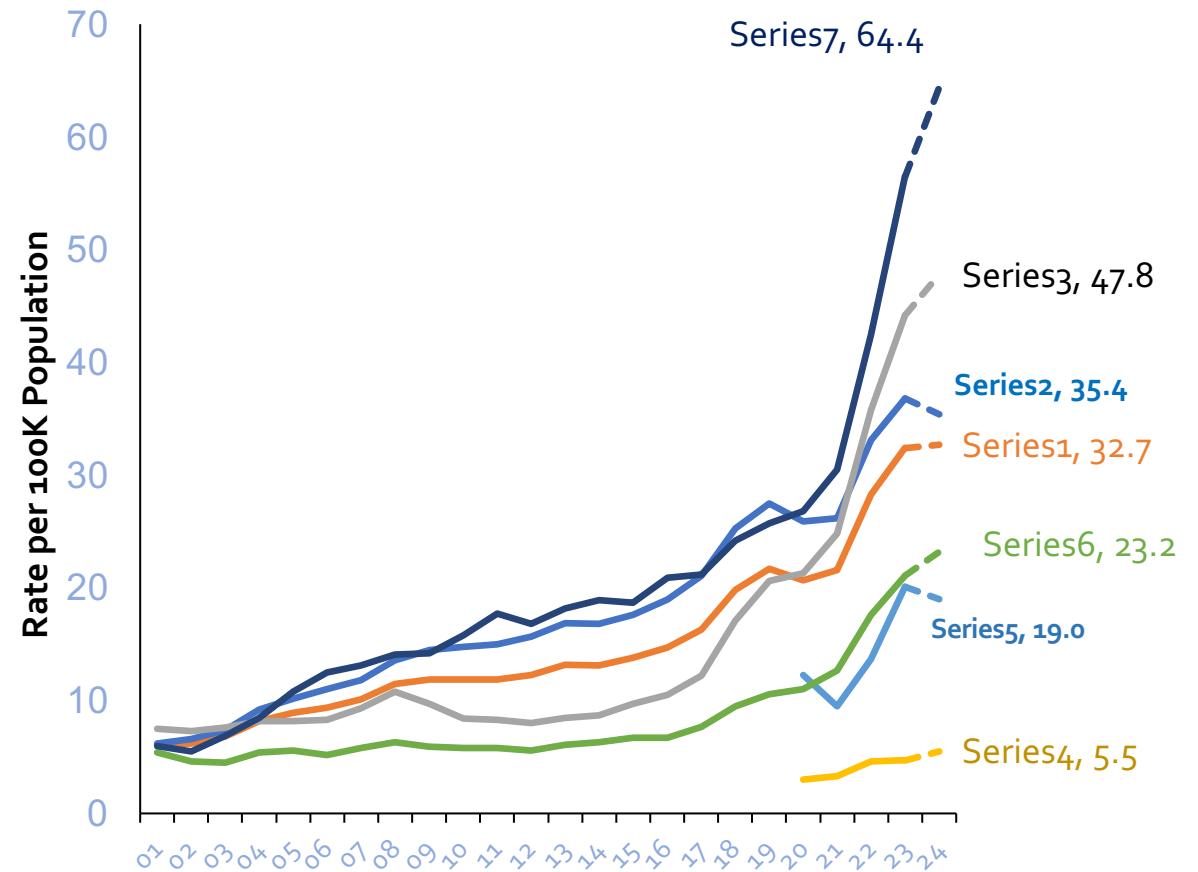**Emerging Issues in the Opioid Crisis: Collision of COVID-19 on Opioid Overdose and Treatment**

Overdose Deaths by Drug

108,262 reported deaths in 2022 (provisional)
82,052 from Opioids (Prescription and Illicit)

Synthetic opioids, fentanyl , 74,061

Methamphetamine,…

Cocaine, 27,627

Natural & semisynthetics and methadone, 14,753

Heroin, 5,880

Number of overdose deaths

—— Final data
---- Provisional

Note: Provisional data Source: The Multiple Cause of Death CDC

Overdose Death by Race

Series7, 64.4

Series3, 47.8

Series2, 35.4

Series1, 32.7

Series6, 23.2

Series5, 19.0

Series4, 5.5

Rate per 100K Population

NCHS, National Vital Statistics System. Provisional data for 2022

Pain – Public Health Crisis and Individual Effects

Nationwide prevalence of pain is high

- 50 million adults with chronic pain
- 25 million report severe pain daily
- 20 million with high impact chronic pain (lasts more than 3 months & interferes with life: school, work, social ,etc.)
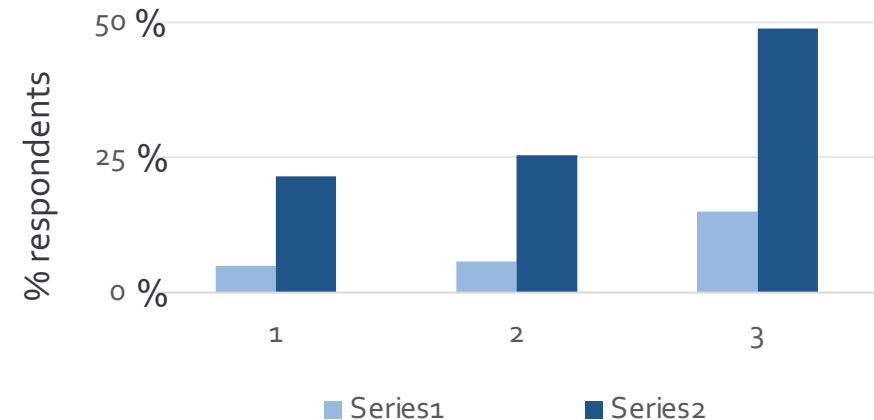
More rural than urban dwellers report pain

- 28% of rural & 16% of urban residents with chronic pain
- 11% of rural & 6% of urban residents with high impact chronic pain

Pain prevalence increases with age
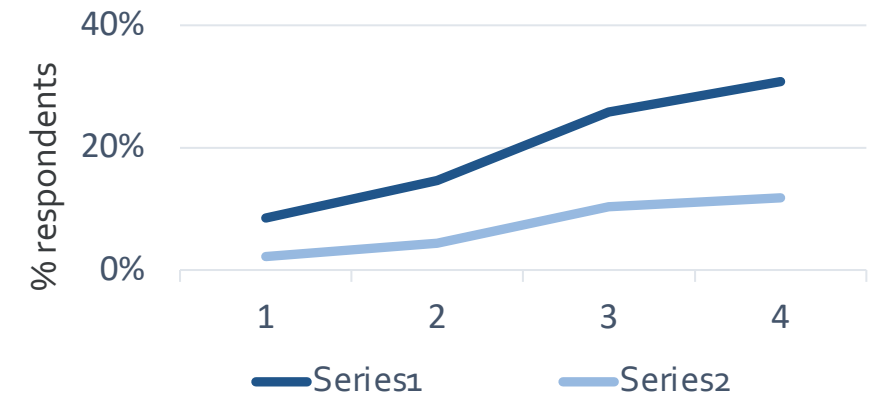
Chronic pain interferes with life

ADL = activities of daily life

HEAL By the Numbers

- Since 2018, **>1,800** research projects in **all 50 states**, totaling over **$3 billion**
- Collaboration across **18** NIH Institutes and Centers
- **42** FDA submissions for investigational new dru or devices
- **300+** clinical trials under way
- Active ongoing partnerships with communities, federal, state, and local agencies, private sector companies, and academia

HEAL Progress

- First-in-Human **clinical trial of antibody** to prevent fentanyl overdose
- Phase 1 clinical trial of **non-narcotic small molecule analgesic** for acute and chronic pain
- Real-time measurement of **chronic pain signature**
- **Buprenorphine** treatment is safe and effective for people who use fentanyl
- New **standard of care for infants** born dependent on opioids published in April is already influencing state-level practice guidelines
- HEAL research **informs work by SAMHSA** to determine needs for naloxone and to create coalitions in communities
- New programs:
  - **Native** Collective Research Effort to Enhance Wellness (N CREW) will fund community-driven research to address overdose, substance use, mental health & pain – to be funded FY24
  - Prevention and Management of Chronic Pain in **Rural** Populations – launched FY23

Pandemic Preparedness

ReVAMPP

R&D of vaccines and monoclonal antibodies against select virus families with pandemic potential

→ **Awards expected next year**

Pan-Coronavirus Vaccine

R&D of vaccines with broad protection against SARS-CoV-2 variants and multiple groups of coronaviruses

→ **Approximately $62M awarded to 7 grants**

PREMISE – Microbial & Immune Surveillance and Epidemiology

Generating reagents and data resources to integrate serologic and immune discovery into product development for potential pandemic pathogens

→ **NIAID Vaccine Research Center program**

AViDD Antiviral Drug Discovery

R&D of oral antiviral candidates to treat SARS-CoV-2 and other pathogens with pandemic potential

→ **Approximately $577M awarded** to 9 comprehensive research centers

Project NextGen

R&D of next-generation vaccines that are effective, durable, and offer broad protection against SARS-CoV-2 transmission

→ Will use existing infrastructure and network sites to evaluate **up to 10 vaccine candidates** for safety and immunogenicity trials
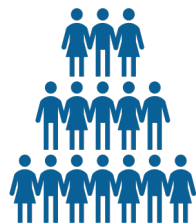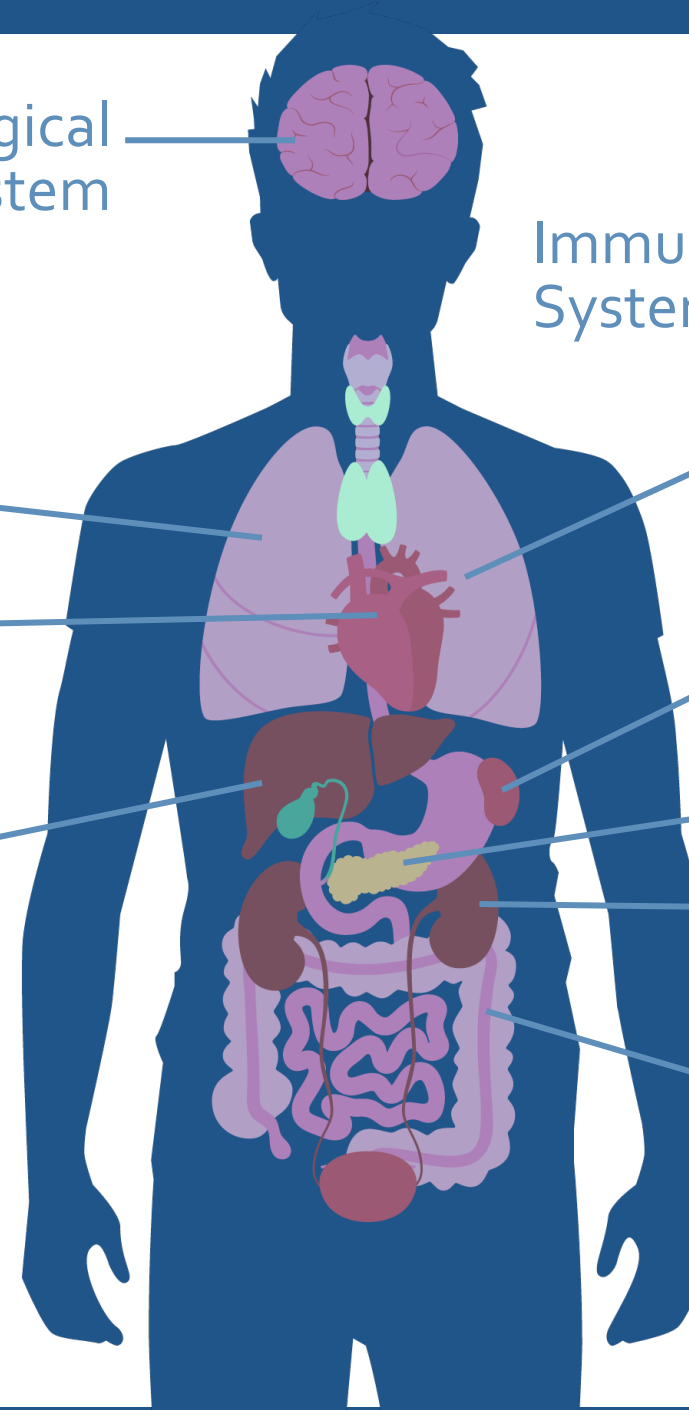
RECOVER Clinical Trials

Viral Persistence & Immune Dysregulation (enrolling)

Neurologic/Cognitive Dysfunction (enrolling)

Autonomic Dysfunction

Sleep Disorders

Cardiopulmonary/Exercise Intolerance/Fatigue

Accelerating Medicines Partnership®

Goal: Unite resources of NIH and private partners to identify better targets so we can develop better drugs at a faster pace.

10
projects

$834M
Total investment

9+
years

34
industry partners

16
NIH Institutes and programs

37
Nonprofits

AMP® Projects Update

2014 projects 2nd phase efforts		
Alzheimer's Disease 2.0	Common Metabolic Diseases	Autoimmune & Immune-Mediated Diseases

Projects initiated 2017-2022			
Parkinson's Disease	Schizophrenia	Bespoke Gene Therapy Consortium	Heart Failure

Projects in development			
Parkinson's Disease and Related Disorders	**ALS**	Systems Biology of Inflammation	Cell-Based Therapy Consortium

Celebrating the 10th Anniversary of AMP®

- Scientific symposium February 5-6, 2024, in North Bethesda, MD:

  o Highlight successful innovation and collaboration in each of the individual AMP project areas

  o Provide a forum for discussions and cross-collaboration in the broader AMP research community`

Science Highlights

"Brain Atlas" Paves Way for New Insights

- International effort: highly detailed cellular maps of adult and developing human brains, along with the brains of other animals.

- Characterized more than 3,000 human brain cell types

- Could help lead to new insights for improving treatments for a host of mental conditions and brain disorders

A list of all the papers part of the brain atlas research is available: https://www.science.org/collections/brain-cell-census *.*
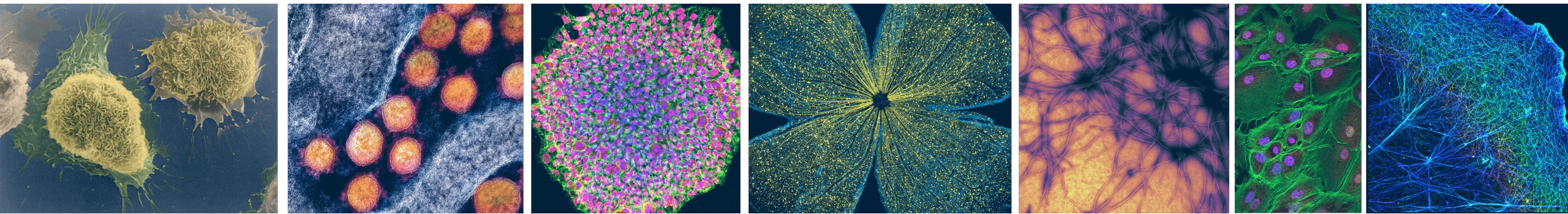
NIH

Turning Discovery Into Health