

Director's Update

*126th Advisory Committee to the Director
June 8, 2023*



Lawrence A. Tabak, DDS, PhD
Acting Director, NIH
Department of Health and Human Services



Topics for Today

- NIH Leadership Changes
- Awards
- SRLM Groundbreaking
- NIH Virtual Tour
- DEIA Strategic Plan
- UNITE Update
- Simplifying Review Criteria
- COVID Updates
- Initiatives updates
- Transitions



Topics for Today

NIH Leadership Changes

- **NIH Leadership Changes**
- Awards
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Nominee for NIH Director



Monica Bertagnoli, MD

Acting Associate Director for Legislative Policy and Analysis



Lauren Higgins

Director, Office of Dietary Supplements



Stefan M. Pasiakos, PhD, FACSM

Acting Associate Director for AIDS Research



Bill G. Kapogiannis, MD

Acting Associate Director for Behavioral and Social Sciences Research



Wendy Smith, PhD

Director, NIH Tribal Health Research Office (THRO)



Karina L. Walters, PhD, MSW

Topics for Today

Awards

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Service to America Awards 2023

Finalists



Arang Rhie, PhD

Adam Phillippy, PhD

Sergey Koren, PhD

and the Telomere-to-Telomere Team

Service to America Awards 2023
Paul A. Volcker Career Achievement Finalist



Eric J "Rocky" Feuer, PhD

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SRLM Groundbreaking

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**Surgery, Radiology and Laboratory Medicine
Wing of the Clinical Center**

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NIH Virtual Tour


NIH National Institutes of Health
Turning Discovery Into Health

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For Researchers
NICHD Zebrafish Research Section




← →

Related

- NICHD Zebrafish Research Section Related Links
- Building 6

Stops

- NIH Welcome and Overview
- Office of Intramural Training and Education



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Topics for Today

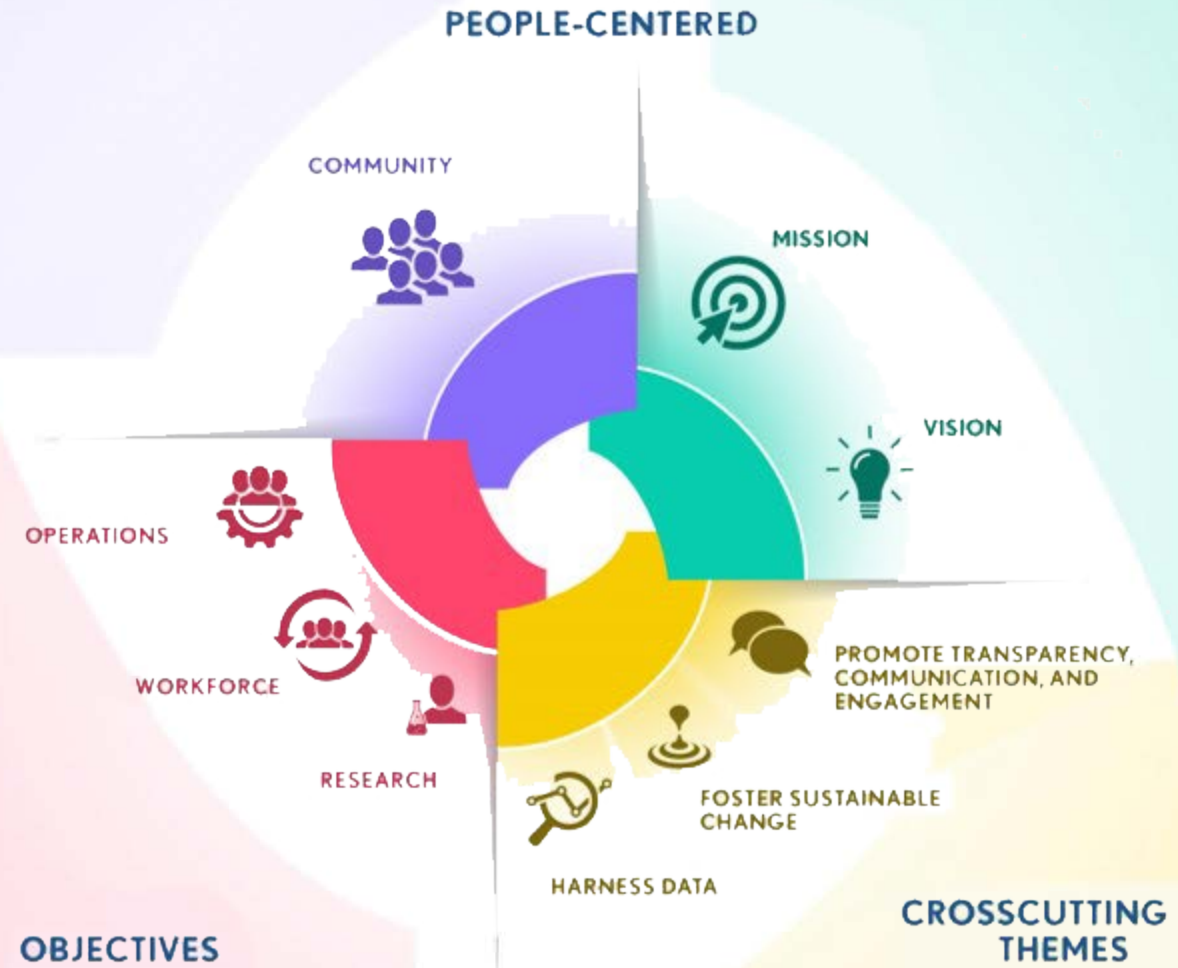
DEIA Strategic Plan

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New NIH DEIA Strategic Plan

- **Development:** Since 2021 by an **NIH-wide Working Group** with **public & NIH input**; reviewed & approved by NIH leadership. Released **March 20, 2023**.
- **Scope: FY 2023-2027.** Articulates vision for integrating DEIA **across all NIH activities**.
- **Organization:** Three priority areas (**objectives**) with common approaches (**crosscutting themes**)
- **Vision:** NIH workforce and research priorities will **reflect our nation's diversity, welcome all people, and advance the NIH mission**



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UNITE Update

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ComPASS

Community Partnerships to
Advance Science for Society

- Program duration: 10 years
- Planned budget: ~ \$153M over a 5-year period

OTA-22-007 (OTA)
Up to 25 awards, FY23



Community-Led, Health Equity
Structural Interventions (CHESIs)

RFA-RM-23-012 (U2C)
Up to 5 awards, FY24



Health Equity Research Hubs
(Hubs)

RFA-RM-23-001 (U24)
1 award, FY23



ComPASS Coordination Center
(CCC)

Recently Enhanced/Released NOFOs



- Science Education Partnership Awards (SEPA) – 17 ICOs
- Research With Activities Related to Diversity (ReWARD) ([PAR-23-122](#))
- Instrumentation Grant Program for Resource-Limited Institutions (S10 - Clinical Trial Not Allowed) ([PAR-23-138](#))
- STrengthening Research Opportunities for NIH Grants (STRONG): Structured Institutional Needs Assessment and Action Plan Development for Resource Limited Institutions (RLIs) ([PAR-23-144](#))

NIH INSTITUTIONAL EXCELLENCE IN DEIA PRIZE COMPETITION

\$1M prize competition administered by COSWD and cosponsored by all 24 NIH funding ICs
– up to 10 awards, of which up to 5 for Resource - limited Institutions

Challenge Goals

Recognize and reward institutions that have identified gaps in DEIA and designed, implemented, and evaluated interventions to address them to improve in DEIA within their faculty, postdoctoral scholars, and student bodies.

Identify effective practices for enhancing DEIA within faculty, postdoctoral scholars, and student bodies that are feasible and can be disseminated for adoption by other institutions.

NIH INSTITUTIONAL EXCELLENCE IN DEIA PRIZE COMPETITION

Key Dates

- **Prize launch:** April 4, 2023
- **FAQ webinar:** May 17, 2023
- **Entry period ends:** September 26, 2023
- **Winners announced:** December 2023

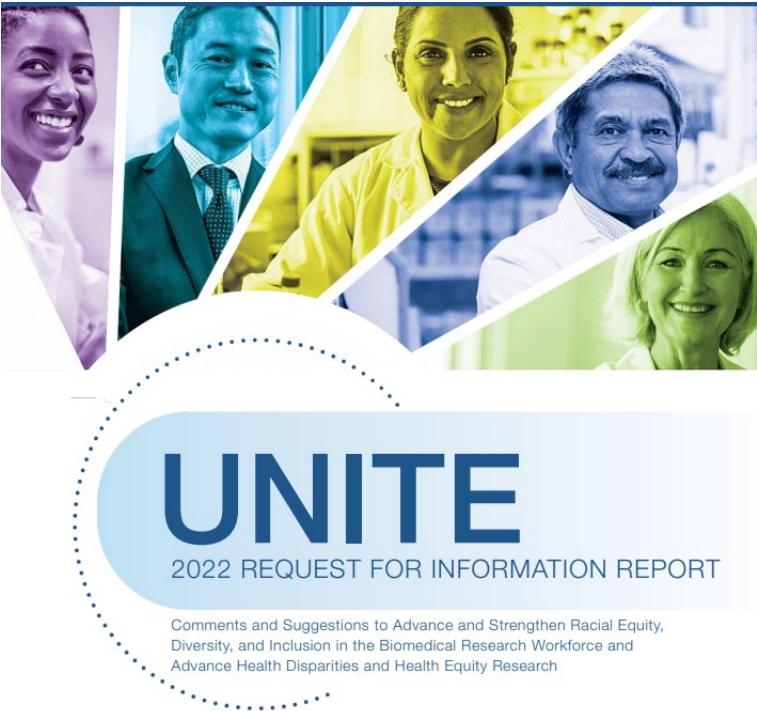


Visit the nihdeiaprize.org to review the eligibility and participation rules and to submit a written entry.

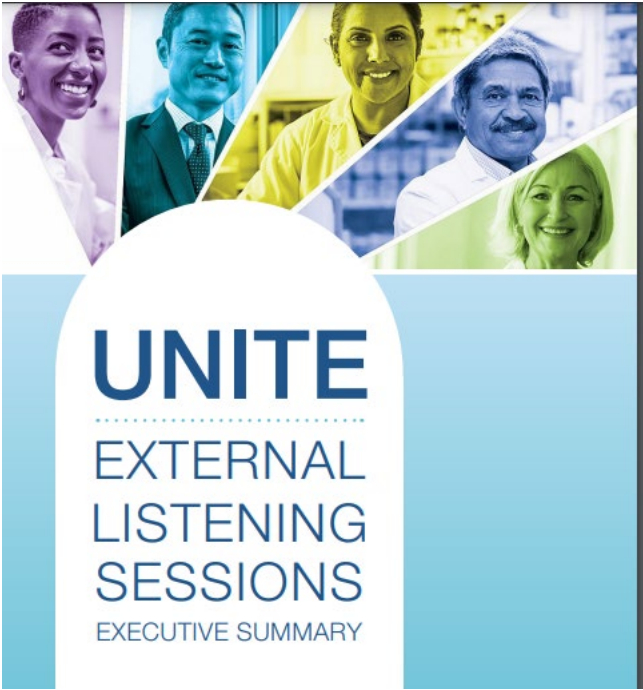
New UNITE Reports



RFI Report



External Listening Session Report



Topics for Today

Simplifying Review Criteria

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Simplified Review Framework for RPGs

Goal: To facilitate the identification of the strongest, potentially highest-impact research

Reorganization of review criteria into three factors. **All affect overall impact score.**

- **Factor 1: Importance of the Research** (*Significance, Innovation*) - scored 1-9
- **Factor 2: Rigor and Feasibility** (*Approach*) - scored 1-9
- **Factor 3: Expertise and Resources** (*Investigators, Environment*) - rated as appropriate or gaps identified

Most Additional Review Considerations (no bearing on overall impact) removed from first-level peer review.

RFI closed in March with >800 responses (~780 individuals, 30 scientific societies, 23 academic institutions):

- **Majority were very supportive** - not surprising; recommendations developed with significant input from the extramural scientific community
- Minority felt that Factor 3 should be scored; smaller minority suggested blinded reviews
- Most called for **strong training resources** to socialize the change for reviewers, chairs, and staff

Next steps? Trans-NIH implementation committee with multidimensional expertise in peer review, reviewer training, staff training, eRA systems, communications, policy – will consider RFI input, develop roll-out strategy

Simplifying Review: NRSA Fellowships

Goal: To facilitate the mission of scientific peer review- identify highly promising research scientists of the future

Background: Persistent concerns that NRSA fellowship review disadvantages some highly-qualified, promising applicants. Concerns are supported by data analysis of 6K fellowship applications:

- The majority of fellowship applications are submitted by a small number of institutions and applications from those institutions do better in review
- Review outcomes for fellowships improve as the rank of the sponsor increases
- Details and data: [https://public.csr.nih.gov/sites/default/files/2022-11/CSRAC Fellowship review WG report September 2022 final.pdf](https://public.csr.nih.gov/sites/default/files/2022-11/CSRAC_Fellowship_review_WG_report_September_2022_final.pdf)

Major Recommendations

- **Revise the review criteria**
- **Revise the application for alignment with the criteria**

RFI open through June 23, 2023. Details and RFI submission at: <https://grants.nih.gov/policy/peer/improving-nrsa-fellowship>

Request for Information (RFI) on Recommendations for Improving NRSA Fellowship Review

Notice Number:
NOT-OD-23-110

Key Dates

Release Date:
April 24, 2023

Response Date:
June 23, 2023

Topics for Today

COVID Updates

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COVID-19 Pandemic: NIH-Wide Review of Lessons Learned

WORKFORCE

Safety, Adaptability, Resources

- Ensure health, safety and welfare of staff
- Manage burnout
- Prepare qualified people at all levels to support timely decision making and manage essential functions

OPERATIONS

Safety, Adaptability, Resources

- Create pandemic preparedness plan
- Improve NIH supply chain
- Establish funding mechanisms for emergency response, incl policies for grants and contracts

INFRASTRUCTURE

Safety, IT, Resources

- Single POC to manage NIH facility decisions
- Assess technology across ICOs – workforce connectivity
- Facilitate hybrid and telework meetings

COMMUNICATIONS

Safety, Messaging, Adaptability

- Have community partners ready to disseminate information
- Reduce mis/disinformation
- Develop centralized NIH approach for internal response communications

INNOVATIVE SCIENTIFIC COLLABORATIONS

Adaptability, Monitoring, Resources

- Operationalize “Crisis Science” model
- Create incentives and protocols to easily redirect research resources
- Improve asset assessment, info sharing, archiving

RECOVER: Researching COVID to Enhance Recovery

A PATIENT-CENTERED, INTEGRATED, ADAPTIVE RESEARCH NETWORK



SCIENTIFIC AIMS

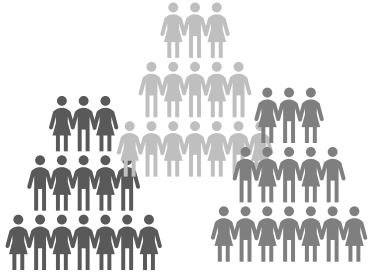
1 Understand the range of recovery and changes in our bodies over time.

2 Define risk factors, number of people getting Long COVID, and if there are specific, different Long COVID types.

3 Study how Long COVID progresses over time and how that may relate to other illnesses.

4 Identify possible treatments to help with Long COVID symptoms.

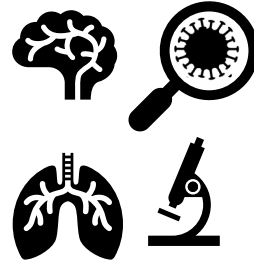
RECOVER Achievements and Future Directions



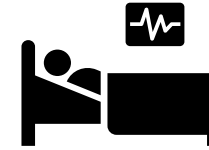
Largest, diverse, deeply characterized clinical cohort of PASC patients
(Adult completion Q3; Pediatrics Q4)



Cohorts that support **deep and longitudinal characterization** of PASC patients



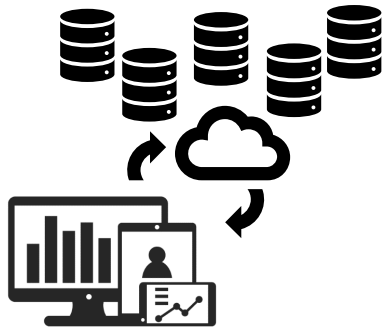
40 + pathobiology studies that will characterize **pathophysiology** of PASC



5 master protocol-driven **platform clinical trials** poised to launch



EHR studies providing insights on **PASC prevalence, risk factors, impact, disparities**



Analysis of **60 million records** with **>7 million COVID cases** across **diverse populations**



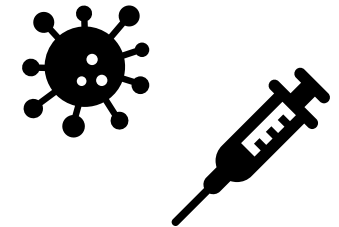
Biomarker testing underway



Mobile health platform; deployment of the **smartphone app**



Collaborative patient **community engagement**



Characterized impacts of **different variants** and **vaccination**

Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

- Ongoing clinical trials
 - ACTIV-2D/"SCORPIO-HR" (novel Shionogi oral antiviral in outpatients)
 - ACTIV-4 Host Tissue (oral fostamatinib in inpatients)
 - ACTIV-6 Repurposed Drugs (oral montelukast in outpatients)
 - STRIVE (novel Shionogi oral antiviral in inpatients) - aims to maintain a global clinical trials infrastructure for pandemic preparedness



ACTIV Status and Outputs

Enrollments & Activation



23,000+ Patients



enrolled into ACTIV trials



312 Sites enrolling

Publications



49 Scientific Publications
in **7 Medical Journals**



Cited 1985 times
according to Google Scholar

Agent Reviews & Authorizations

800+

Agents reviewed

34

Agents and combinations fully enrolled and completed testing

6

Agents proven efficacious against COVID-19

- **EUA ACHIEVEMENTS:**

- Lilly LY-CoV-555
- Bii Bio Bii-196/Bii-198
- AstraZeneca's AZD7442 (IV) applied for EUA intending to have ACTIV outpatient data noted in the submission package

- **Molnupiravir and paxlovid**, granted EUA, used the ACTIV protocols

- ACTIV-4A work on heparin and other anticoagulants **changed clinical practice**

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Cancer MoonshotSM

December 2016
21st Century Cures Act

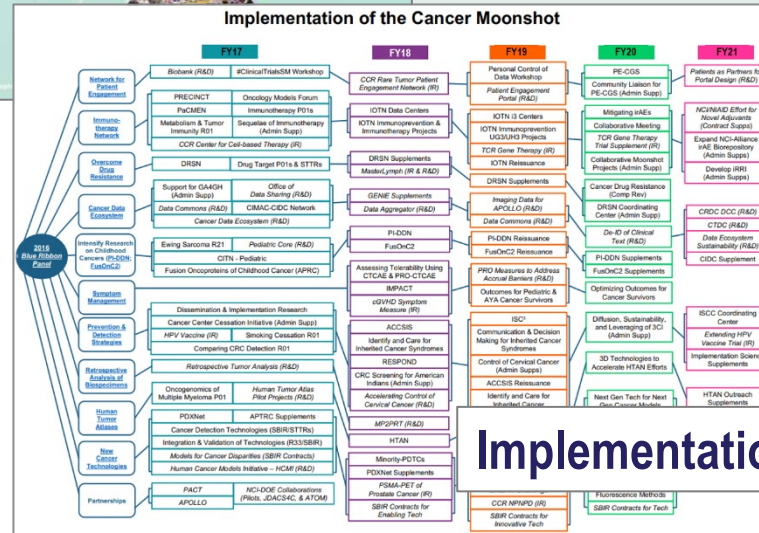
Precision Medicine Initiative
 \$1.45 billion over 10 years

Beau Biden Cancer Moonshot
 \$1.8 billion over 7 years

BRAIN Initiative
 \$1.511 billion over 10 years

Regenerative Medicines
 \$30 million over 4 years

Cancer Moonshot Blue Ribbon Panel Report



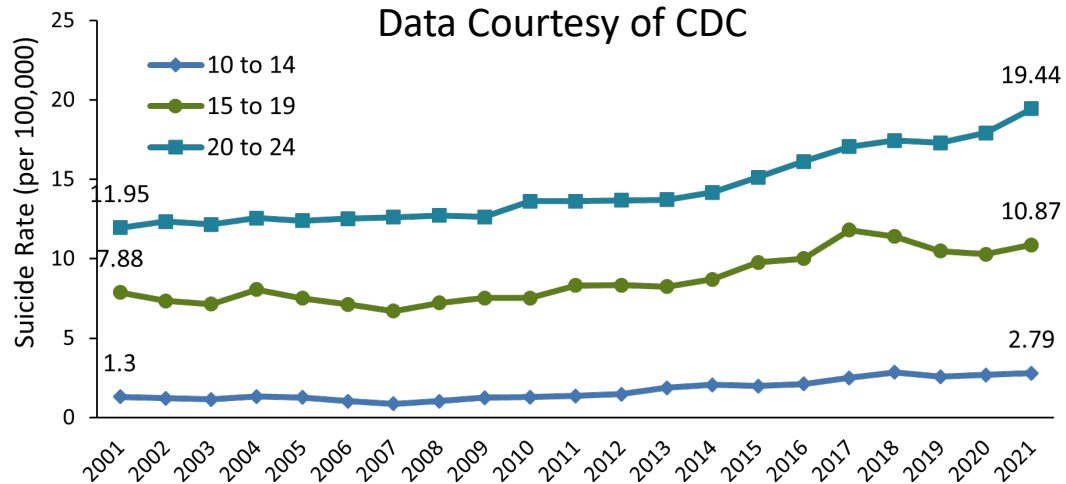
Implementation



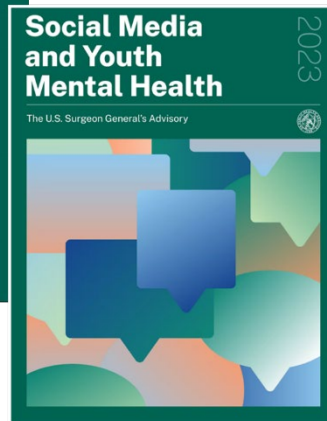
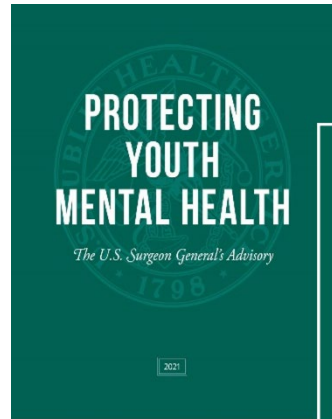
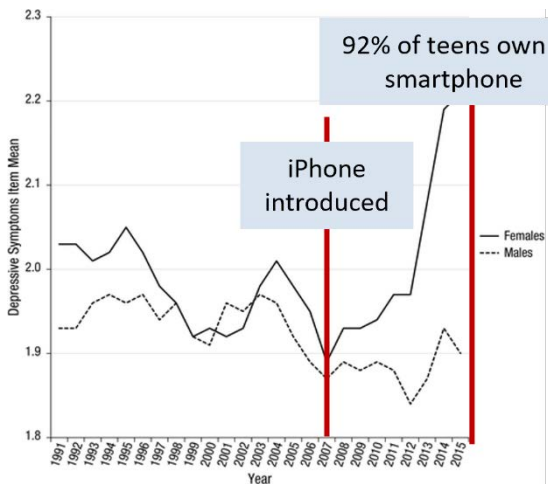
February 2022
President Biden Reignites the Cancer Moonshot with new goals

NIH is Addressing the Youth Mental Health Crisis

Crude Suicide Rates Among Youth in the United States (2001-2021)

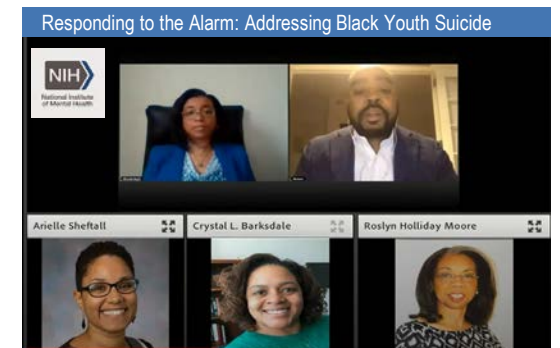
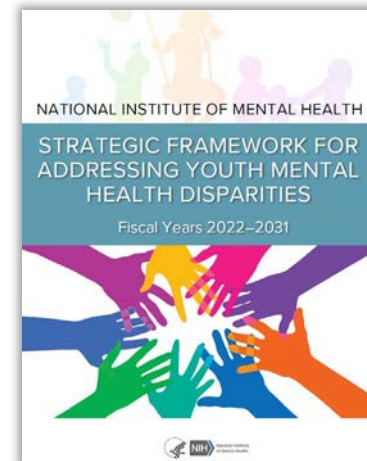


Adolescents who spent more time on new media were more likely to report mental health issues

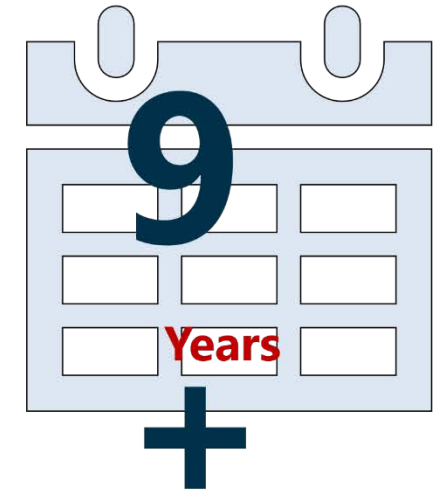


NIH Youth Mental Health Activities and Initiatives

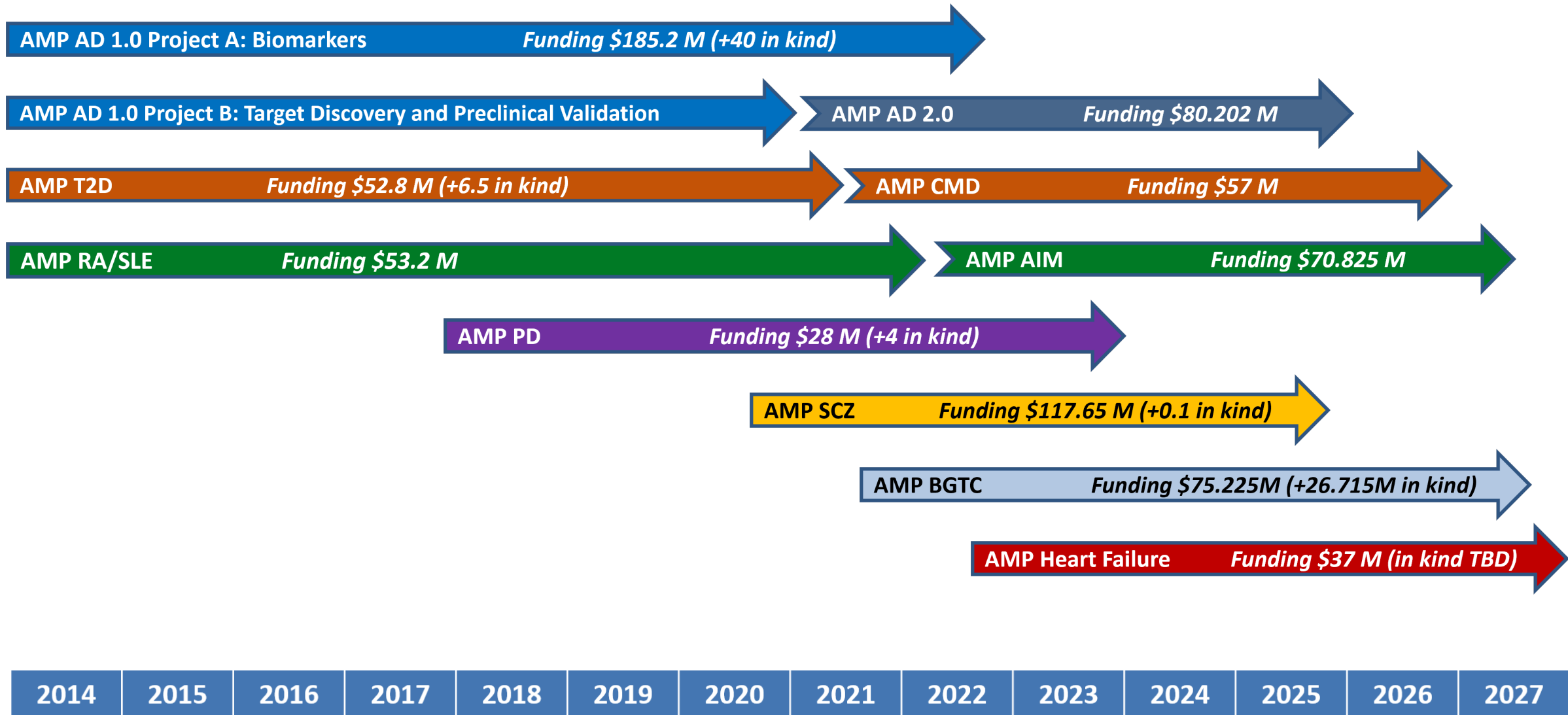
- Bidirectional Influences Between Adolescent Social Media Use and Mental Health (RFA-MH-23-115/-116)
- Understanding Suicide Risk and Protective Factors among Black Youth (RFA-MH-22-140/141)
- Assessment of Suicide Thoughts and Behaviors among Children and Preteens (NOT-MH-22-086)
- School-Based Suicide Prevention: Promising Approaches and Opportunities for Research (January 2022 webinar)
- Four roundtables: Risk, Resilience, and Trajectories in Preteen Suicide (January-June 2021)



The Accelerating Medicines Partnership® (AMP®) By the Numbers



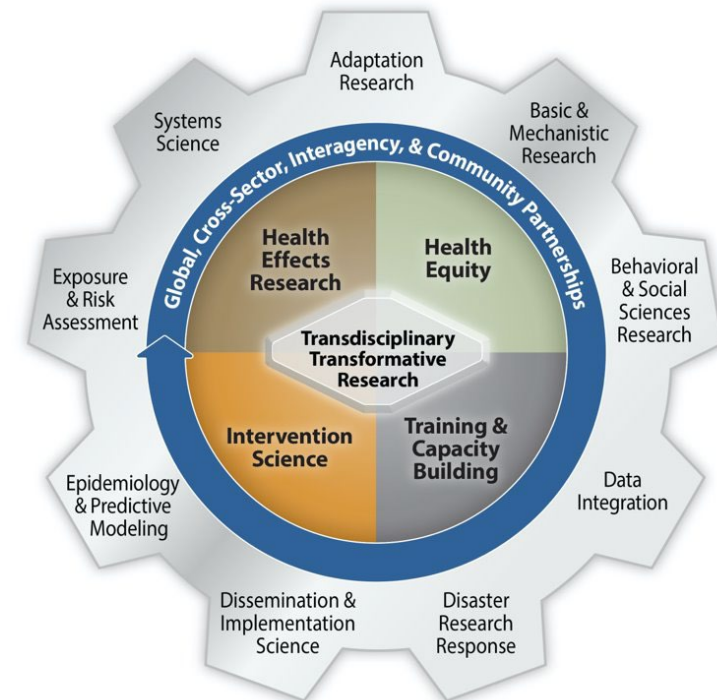
The Accelerating Medicines Partnership® (AMP®) Program timelines





NIH Wide Collaborative Initiative on Climate Change and Health

- **Leadership from an Executive Committee of seven NIH IC Directors**
 - NICHD, NHLBI, FIC, NIMH, NIMHD, NIEHS, NINR
- **Goal:** Reduce health threats across the lifespan and build health resilience in individuals, communities, and nations around the world, especially among those at highest risk.
- **Research strategy focused on multidisciplinary approaches:**
 - Health Effects Research
 - Health Equity
 - Intervention Science
 - Training and Capacity Building
- **Broad assortment of supporting science ranging from:**
 - Basic mechanistic research
 - Data integration
 - Behavioral and social sciences research
 - Disaster research response
 - Etc.



Many Institutes and Centers: One Mission

NCI

NEI

NHLBI

NIA

NIAAA

NIAID

NICHD

NIDA



NINDS

NIAMS

NCATS

NIBIB

NCCIH

NINR

NIMH

NIGMS

NIDDK

NIDCR

NIH HEAL Initiative in 2023

Supporting science-based solutions to the opioid crisis

- Over **\$2.5 billion** in research, more than **1,000** research projects
- **42** research programs, projects in all **50** states
- **314** clinical trials under way
- More than **100** projects addressing back pain alone
- More than **200** projects addressing medications for opioid use disorder
- **41** FDA approvals for investigational new drugs or devices
- Active, ongoing partnerships with federal agencies, private sector, academia, and communities

HEAL is Making a Difference

- New standard of care for infants born dependent on opioids
- Patient-specific chronic pain brain signature
- Buprenorphine safe and effective in the emergency room in the era of fentanyl
- Opioid addiction treatment in jail reduced recidivism by 30%



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NIH...

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[@NIHDirector/Twitter](https://twitter.com/NIHDirector)

Turning Discovery Into Health

