

NCI Principal Deputy Director's Report

Cancer Research: Progress, Opportunities and Challenges

Douglas R. Lowy, M.D.

Principal Deputy Director, National Cancer Institute

90th Meeting of the NCI Council of Research Advocates (NCRA)

October 4, 2023

@NCIDrDougLowy

@TheNCI

Welcome!



Hartley M. Lee Jones

Research Advocate, SWOG Cancer Research Network
Portland, Oregon



Desiree A. H. Walker

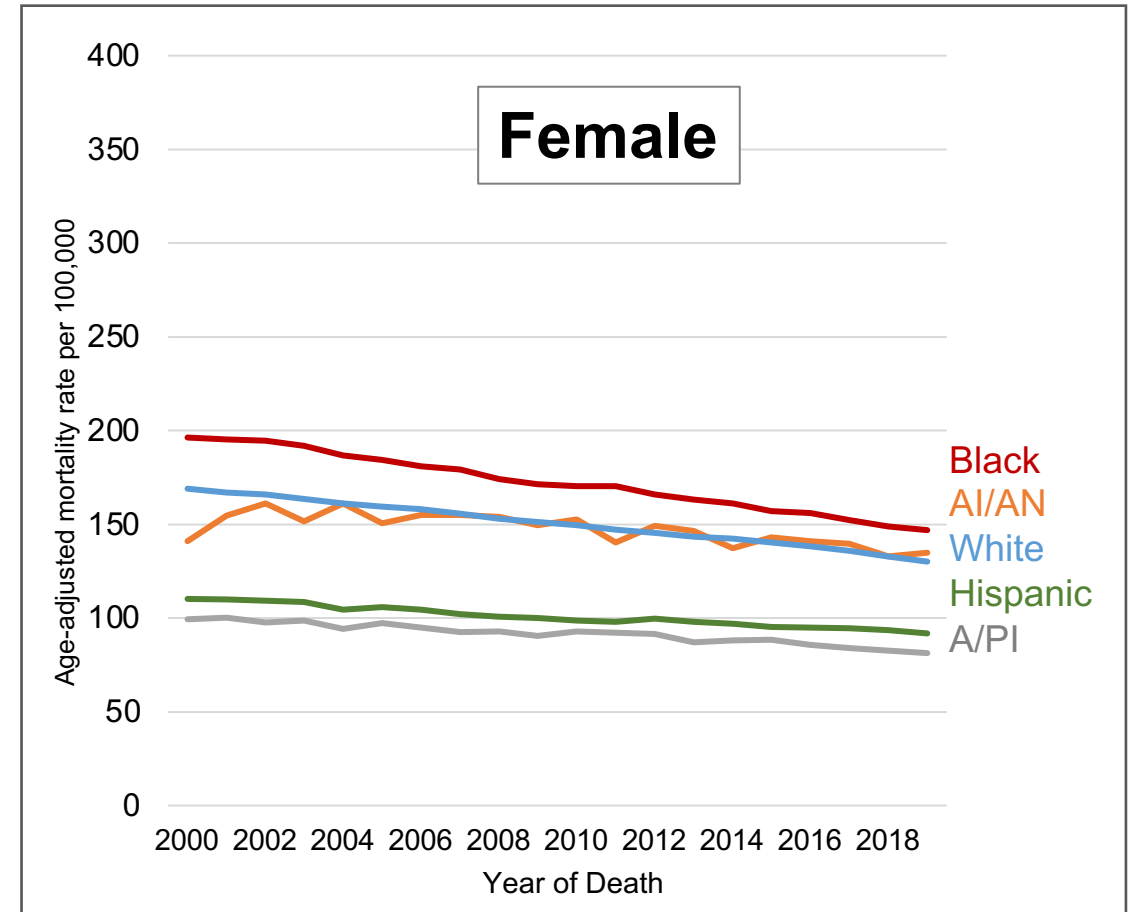
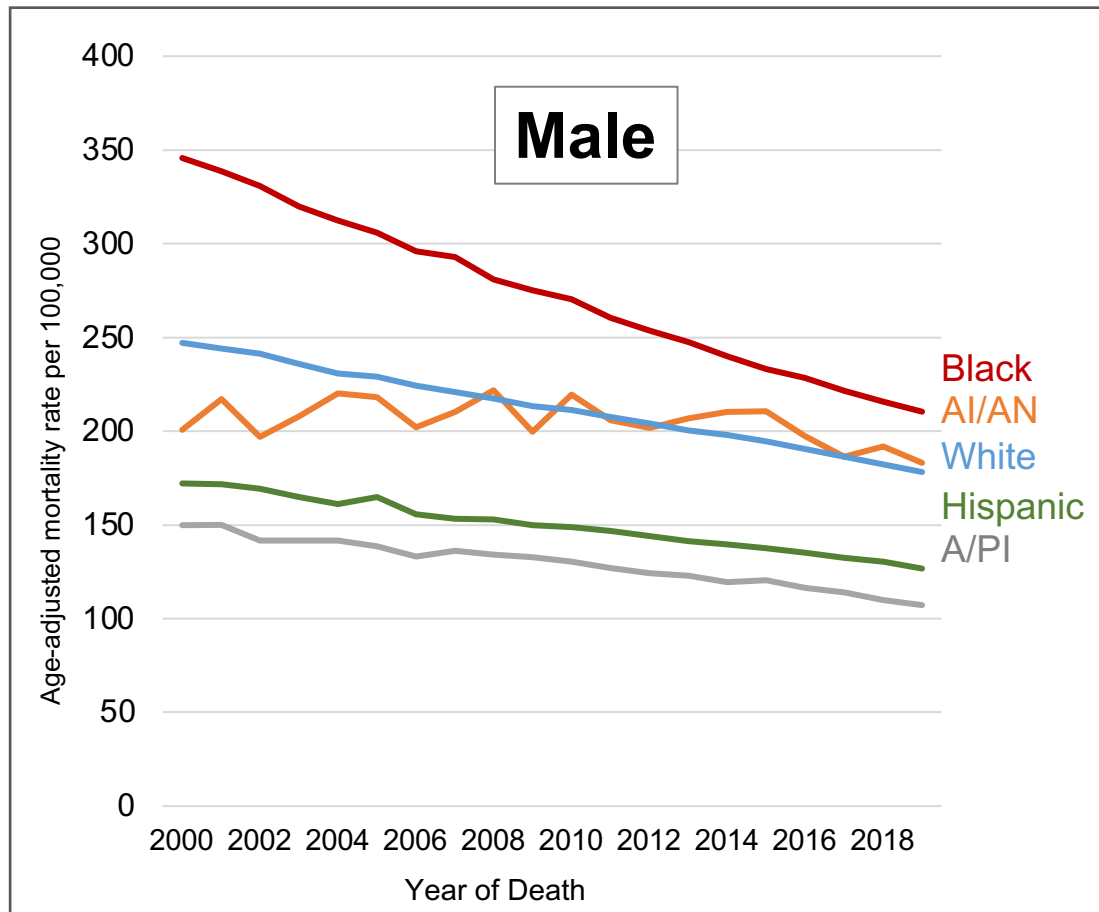
President, Board of Directors Young Survival Coalition, Inc.
New York, New York

Today's Talk – Outline

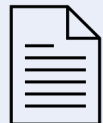
- Evidence of progress and opportunities... but much remains to be done
- NCI Budget Outlook
- Discussion – Q&A

**Evidence of progress
...but much remains to be done**

Cancer Mortality Trends by Race/Ethnicity (2000-19)



Source: NCI Surveillance, Epidemiology, and End Results Program (SEER), seer.cancer.gov



For more, see Lawrence, et al: Trends in Cancer Mortality Among Black Individuals in the U.S. From 1999 to 2019 – *JAMA Oncology*, May 19, 2022

Uterine cancer death rates rising, highest among Black women in U.S.

- **Black women are 2x as likely to die of uterine cancer** compared to other racial and ethnic groups.
- Most of the mortality increase is attributable to non-endometrioid uterine cancer (predominantly uterine serous carcinoma), **which disproportionately affects Black women.**
- Non-endometrioid cancer mortality **increased 3.5% per year for Black women and 6.7% for Hispanic women** between 2010-2017.



There is an urgent need for new research in the affected populations.



Clarke et al. Racial and Ethnic Differences in Hysterectomy-Corrected Uterine Corpus Cancer Mortality by Stage and Histologic Subtype. *JAMA Oncology*. May 5, 2022

NCI Workshop: The Diverse Aspects of Uterine Serous Cancer

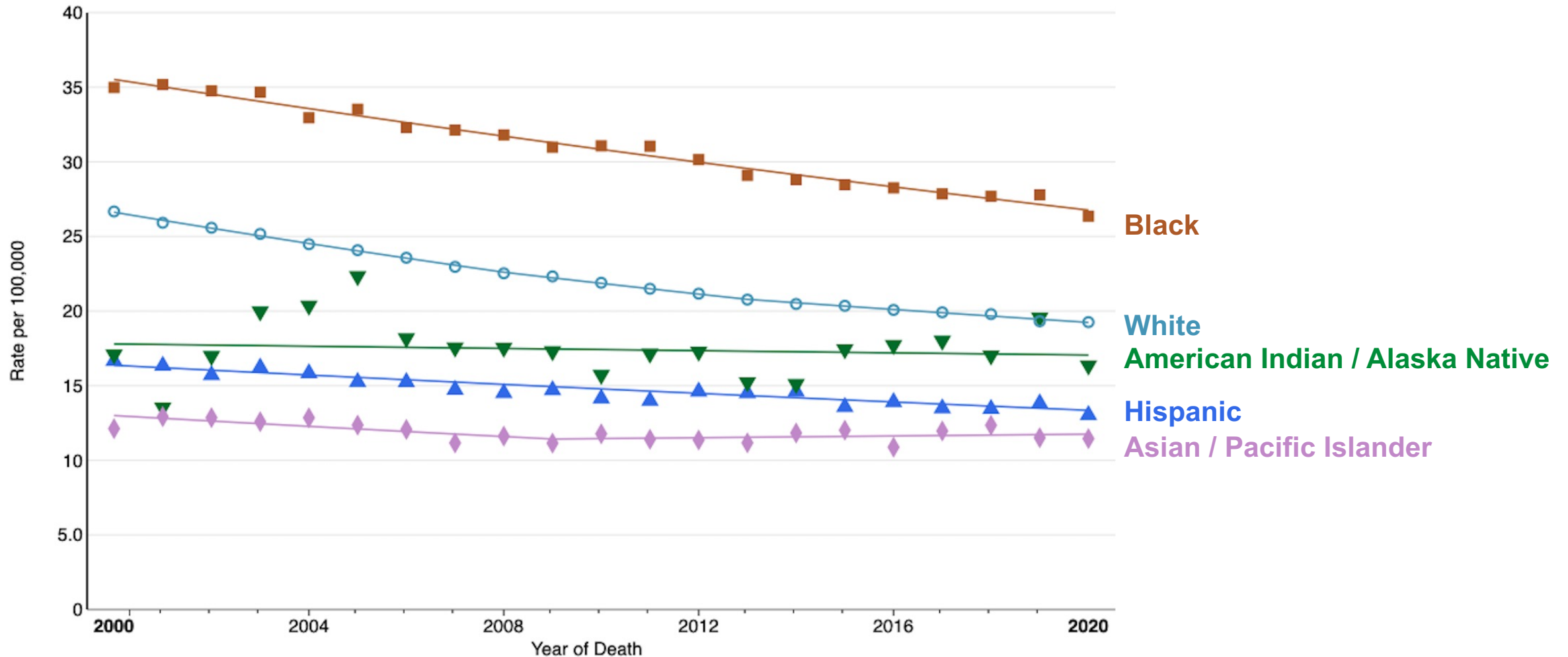
June 22-23, 2023

Key takeaways:

- ✓ Spread the word to new investigators and grant reviewers that uterine serous cancer (USC) is “not your grandmother’s cancer.”
 - There’s a lot to study – it’s a fertile field.
- ✓ Development of syngeneic, clinically relevant mouse models of USC is critical to understanding its biology and evolution.
- ✓ Molecular signatures, undiscovered targets, and disparities among defined populations are crucial to furthering the field.
- ✓ Development of organoids and patient-derived xenografts (PDX) from diverse patients would be useful.



Trends in Female Breast Cancer Mortality Rates By Race/Ethnicity in the U.S. (2000 – 2020)



Recent FDA Approvals for Breast Cancer Treatment

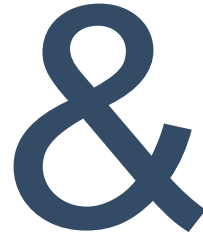
Date	Approval / Treatment
March 3, 2023	Expanded early breast cancer indication for abemaciclib with endocrine therapy
February 3, 2023	Sacituzumab govitecan-hziy for HR-positive breast cancer
January 27, 2023	Elacestrant for ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer
August 5, 2022	Fam-trastuzumab deruxtecan-nxki for HER2-low breast cancer
May 4, 2022	Fam-trastuzumab deruxtecan-nxki for breast cancer
March 11, 2022	Olaparib for adjuvant treatment of high-risk early breast cancer



Goals of the reignited Cancer Moonshot

- Reduce U.S. cancer death rate by 50% in the next 25 years (*hard*)
 - Overcome cancer disparities (*harder*)
 - End cancer as we know it, for all (*hardest*)
-
- NCI jump-started the reignited Cancer Moonshot in FY23 with funds from the initial Moonshot.
 - ***How can NCI ensure the aspirational goals of the reignited Moonshot become feasible?***

Accomplishing the Goals of the Cancer Moonshot



- Need wider dissemination of current standards of care
- Ensure everyone benefits
- Requires implementation research

- Need more research advances
- Must include cancers that currently have a poor prognosis, rare cancers, and childhood cancers

Cancer Cabinet Meeting to Advance the Goals of the Cancer Moonshot (September 13, 2023)



SEPTEMBER 13, 2023

FACT SHEET: As Part of President Biden's Unity Agenda, White House Cancer Moonshot Announces New Actions and Commitments to End Cancer as We Know It



- President Biden and the First Lady met with the Cancer Cabinet to announce new actions federal agencies and non-governmental organizations are taking to advance the goals of the Cancer Moonshot:
 - ARPA-H Biomedical Data Fabric Toolbox for Cancer
 - Engaging veterans in tobacco cessation programs
 - Developing a two-way data exchange between NCI's SEER program and the VA cancer registry to learn more about the impact of cancer on veterans
 - ...and more at www.whitehouse.gov/briefing-room









**NCI has cancer
research collaborations
with many other
U.S. government
departments and
HHS agencies**

- Department of Defense
- Department of Energy
- Department of Veterans Affairs
- Department of Commerce
- Within the Department of Health and Human Services:
 - Food and Drug Administration
 - Centers for Disease Control and Prevention
 - Health Resources and Services Administration
 - Advanced Research Projects Agency for Health (ARPA-H)...
and many other NIH Institutes and Centers

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.

EIGHT GOALS

-  **Prevent Cancer**
-  **Detect Cancers Early**
-  **Develop Effective Treatments**
-  **Eliminate Inequities**
-  **Deliver Optimal Care**
-  **Engage Every Person**
-  **Maximize Data Utility**
-  **Optimize the Workforce**

EVERYONE HAS A ROLE!

- The White House
- Congress
- National Cancer Institute
- NIH Institutes and Centers
- U.S. Department of Health and Human Services
- Cancer Cabinet
- Professional Societies
- Advocacy Organizations
- Academia
- Industry
- Foundations
- Health Care Providers
- People with Cancer and Other Individuals

CANCER MOONSHOT

Providing the vision and charge for a whole-of-government approach to stimulate collaboration and accelerate progress across the National Cancer Program

Read the plan: nationalcancerplan.cancer.gov

President's Cancer Panel: National Cancer Plan Initial Stakeholder Meeting (September 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

AACR



ASCO

ASPO American Society of Preventive Oncology

ASTRO
AMERICAN SOCIETY FOR RADIATION ONCOLOGY

ACCC
Association of Community Cancer Centers



CEO ROUNDTABLE
ON CANCER

HIMSS

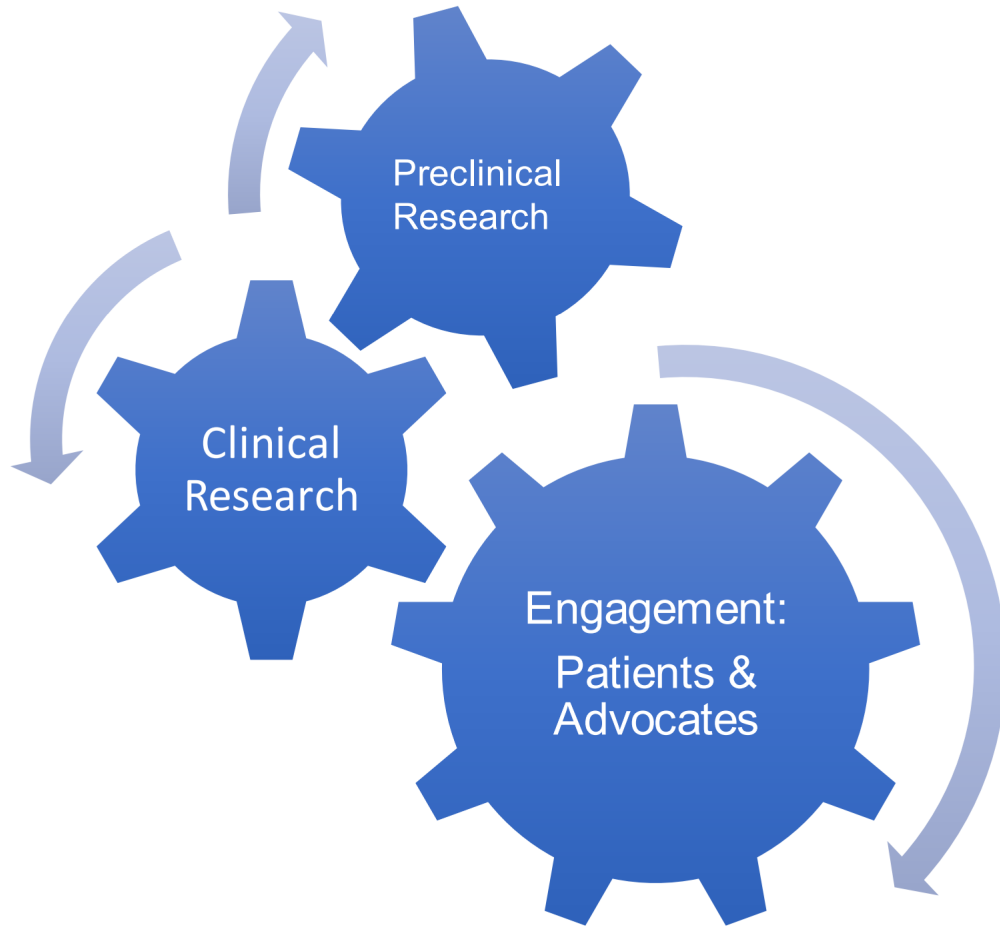
Childhood Cancer Data Initiative (CCDI)

Recent Highlights

- **Release of additional molecular characterization data and clinical data** collected from the Children's Brain Tumor Network, the Pacific Pediatric Neuro-Oncology Consortium, and the Children's Hospital of Philadelphia Division of Genomic Diagnostics
- New improvements to the **CCDI Molecular Targets Platform**
- Launch of new **CCDI Hub**
- New database of **Genotypes and Phenotypes (dbGAP)** resource added to CCDI Data Catalog



MyPART: My Pediatric and Adult Rare Tumor Network



Mission:

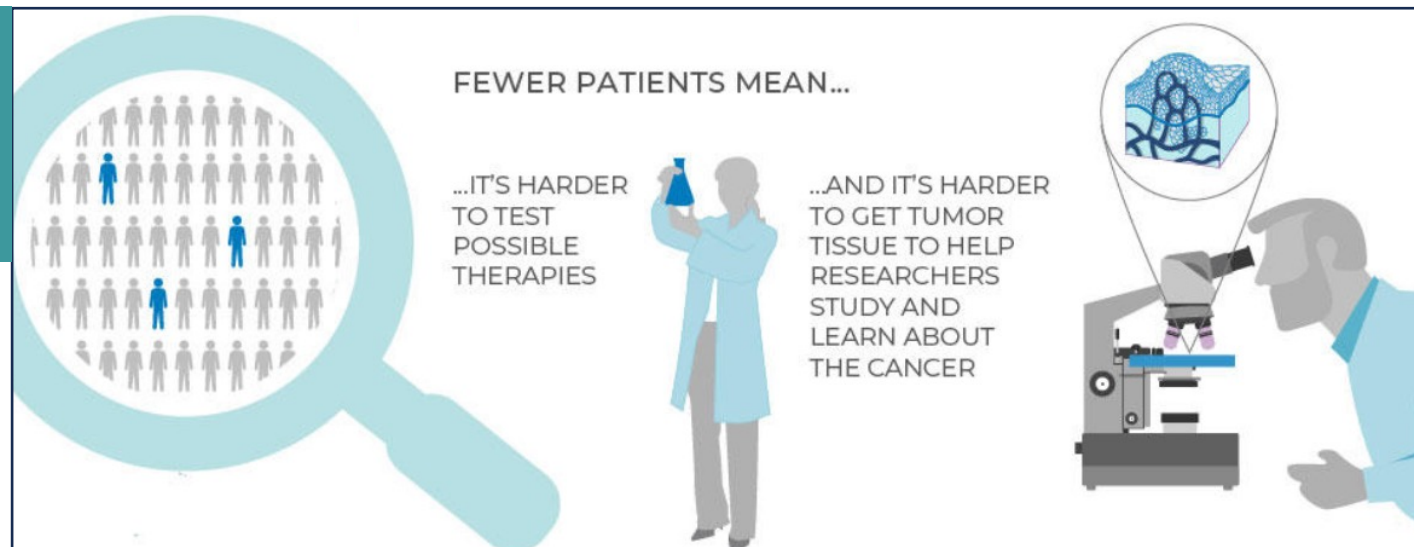
Increase patient and family involvement in rare tumor research to develop new therapies for rare pediatric and adult solid tumors through increased understanding of tumor biology and natural history

Why MyPART focuses on rare cancer research

How rare cancers are defined



Rare cancers are hard to study



MyPART: My Pediatric and Adult Rare Tumor Network



Engaging patients, advocates, and researchers to improve the lives of young people with rare cancers

www.cancer.gov/mypart

- Focusing on rare solid tumors affecting **children, teens, and young adults (<39)**
- Engaging patients, family members, advocates, clinicians, scientists, as **partners in research**
- Collecting longitudinal **molecular, clinical, and patient reported** outcome data through the **Natural History Study of Rare Solid Tumors (NCT03739827)**
- Holding **workshops and symposia** on rare tumors to develop expert consensus
- Hosting **multi-day clinics** for rare tumors to bring patients and nationwide experts together
- Building a **multi-institutional network** of sites to collaborate on data collection
- Proposing to develop new interventions

United States - European Union:

Artificial Intelligence Engagement Seminar Series



The Trans-NCI Artificial Intelligence (AI)
Working Group hosted a series of meetings in
July 2023 on

“Equitable and Engaged AI to Advance Biomedical Research”

Learn more: events.cancer.gov/nci/ai-engagement-series

Diverse subject matter experts from the US and EU engaged in robust discussions and collaborative efforts in the field of equitable and engaged AI.

Focus areas:

- ✓ Privacy preserving AI
- ✓ Community/patient engaged AI for biomedical research
- ✓ Ethical AI and the inclusion of underserved communities

Meeting objectives:

- ✓ Maximize interactivity
- ✓ Facilitate collaboration building
- ✓ Encourage open sharing of information and novel ideas

New Funding Opportunity



**Wortia McCaskill-Stevens, M.D., M.S.
NCORP Director**

**NCI Wortia McCaskill-Stevens
Career Development Award
for Community Oncology and
Prevention Research**

Cancer screening

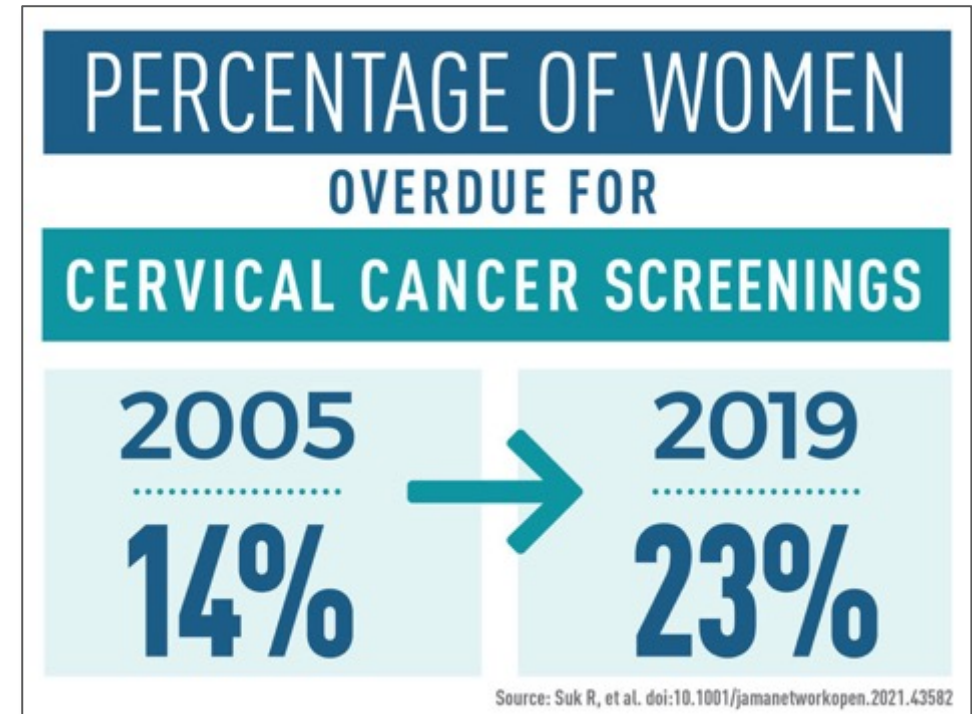
Cancer screening

Instead of aiming for pre-COVID screening rates,
the goal should be to:

- ✓ **Increase screening rates – higher than pre-COVID levels**
- ✓ **Be able to screen for more types of cancer**

Many Women Overdue For Cervical Cancer Screening; Increasing Over Time

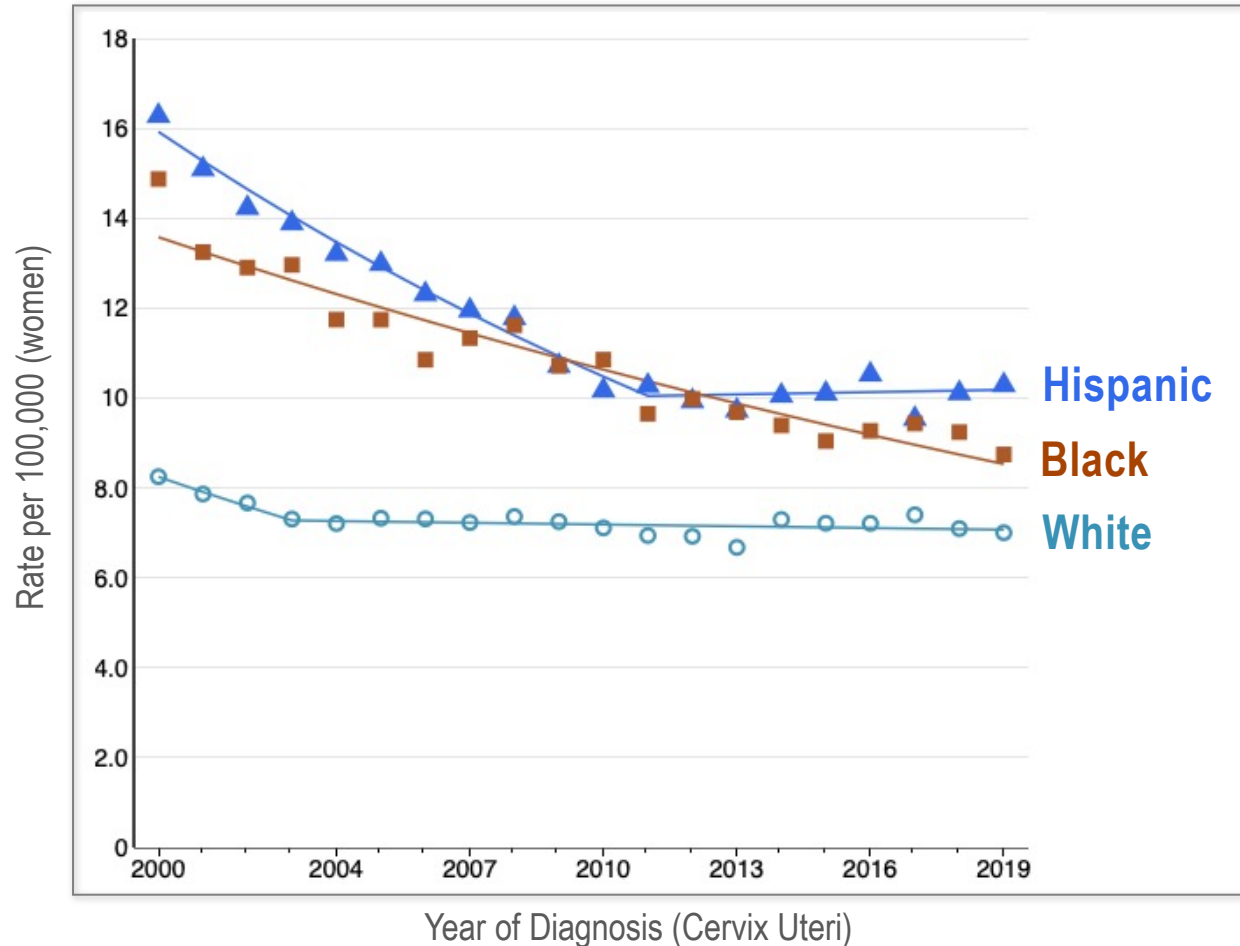
Rates of overdue cervical cancer screening (2019)	
Black	22%
White	20%
Uninsured	42%
Public insurance	28%



The increase in the proportion of women who said they “did not have a recommendation from a health care provider” as reason for lack of timely screening: INCREASED 6% to 12% (2005 to 2019)

Cervical Cancer Incidence and Mortality in the U.S.

**Age-Adjusted Incidence Rates
2000-2019**



Est. new cases/deaths in 2022:

- New cases: 14,100
- Deaths: 4,280

Current Mortality Rates per 100,000 (2020)

Black	3.2
Hispanic	2.5
White	2.1
American Indian / Alaska Native	2.1
Asian / Pacific Islander	1.7

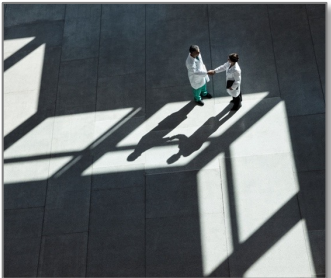
NCI's Cervical Cancer 'Last Mile' Initiative

A public-private partnership bringing together federal agencies, industry, and professional societies – to develop sufficient evidence to enable FDA-approval for self-sampling.



Goal:

Overcome barrier of lack of FDA approval for self-sampling approaches for HPV testing-based cervical cancer screening



Approach:

Engage public and private sector stakeholders to facilitate regulatory approvals for self-sampling



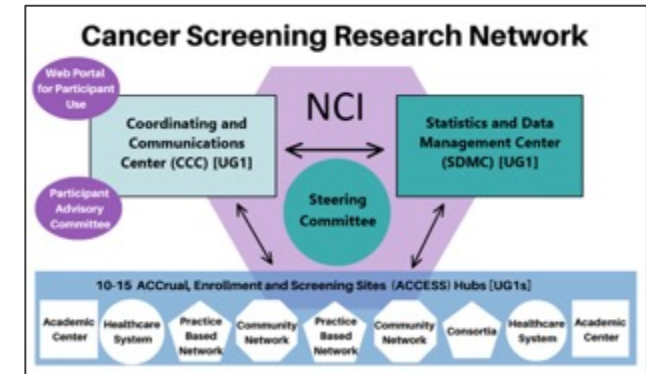
Outcome:

Increase screening access and reduce cervical cancer incidence in underserved and high-burden populations

New: Cancer Screening Research Network (CSRN)

To conduct trials and studies specifically related to cancer screening

- The CSRN will conduct rigorous, multi-center cancer screening trials and studies with **large and diverse populations** in a variety of health care settings.
- Ultimate goal: Reduce cancer incidence and cancer-related morbidity and mortality.



Initial effort of the CSRN:

Vanguard Study on Multi-Cancer Detection

- Goal: to evaluate the effectiveness of new blood tests to detect one or more cancer(s) to **prevent cancer-related deaths**
- Plans to enroll 24,000 healthy people age 45-70 years in 2024
- Larger study will enroll up to 225,000 people

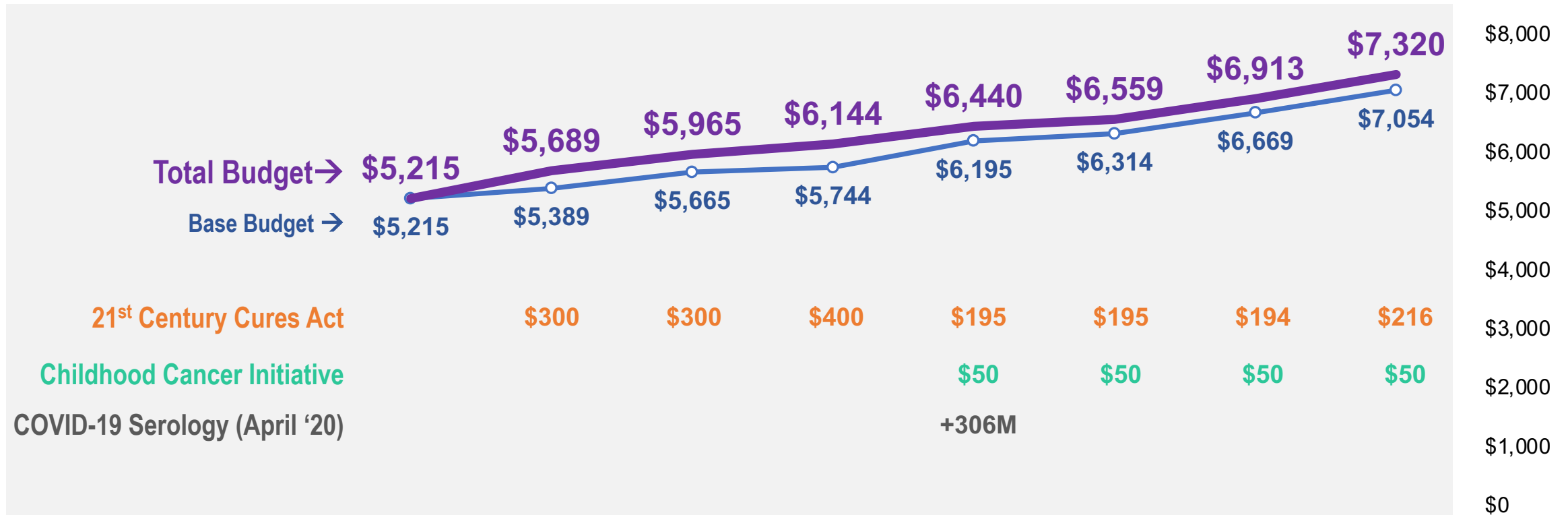
Due to budget constraints, only 7 centers have been funded.



Budget outlook

NCI Appropriations and Paylines (FY 2016 – 2023)

Dollars in millions



		FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
Paylines* (percentile)	Established	10	10	9	8	10	11	11	12
	Early-Stage	12	12	14	14	15	16	16	17

Established investigators: R01
Early-Stage Investigators: R01/R37



NATIONAL CANCER INSTITUTE



Leading Progress against Cancer

NCI Fiscal Year 2025 Professional Judgment Budget Proposal



Available as of September 20, 2023, at:
www.cancer.gov/research/leading-progress

NCI FISCAL YEAR 2025 (FY25) PROFESSIONAL JUDGMENT BUDGET PROPOSAL

(DOLLARS IN MILLIONS)

Prior (FY24) Professional Judgment Budget Proposal	\$9,988*	
Proposed Budget Increase for FY25	\$1,478	<ul style="list-style-type: none"> \$518 Cancer Biology Research \$161 Cancer Prevention Research \$240 Cancer Detection & Diagnosis Research \$338 Cancer Treatment Research \$111 Public Health & Cancer Control Research \$110 Training & Infrastructure
FY25 TOTAL	\$11,466	

**This proposal includes \$1,581 million for the Cancer Moonshot and \$50 million for the sixth year of the Childhood Cancer Data Initiative.*

NCI Fiscal Year 2025 Professional Judgment Budget Proposal

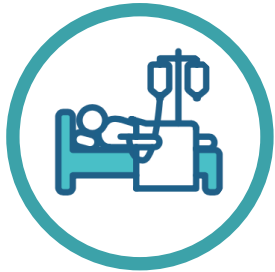
Highlighted Scientific Opportunities



**IMPROVING PATIENTS' LIVES
THROUGH SYMPTOM SCIENCE
RESEARCH**



**HARNESSING THE POWER
OF CANCER DATA**



**REVOLUTIONIZING
CANCER CLINICAL TRIALS**



**UNRAVELING THE
COMPLEXITY OF CANCER
METASTASIS**



**CLARIFYING THE IMPACT OF THE
ENVIRONMENT ON CANCER RISK**

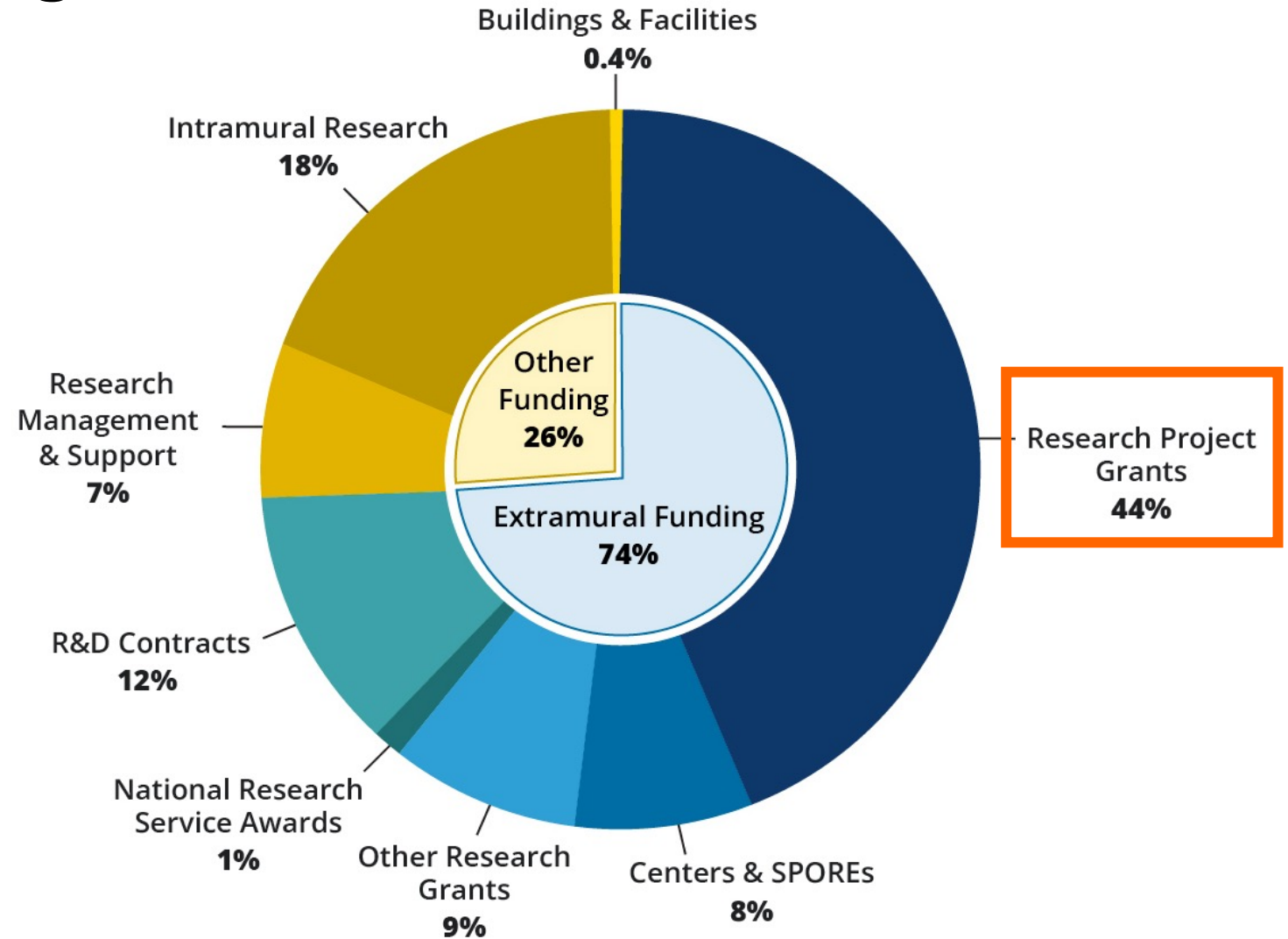
How NCI Spends its Budget

Major areas of NCI's work span more than one of the categories in the chart:

- Clinical trials
- Training & career development
- Basic science

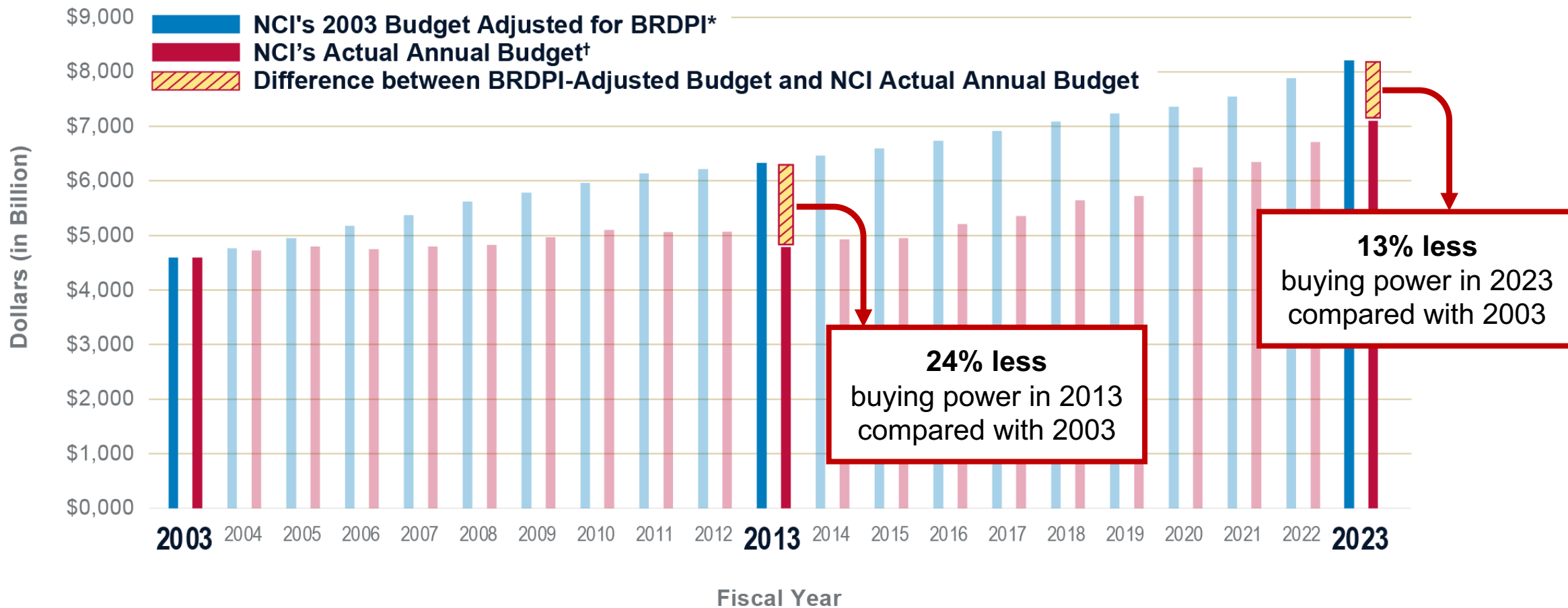
These efforts are funded through multiple mechanisms and approaches, including:

- Intramural research
- Extramural research
- National networks
- Research project grants

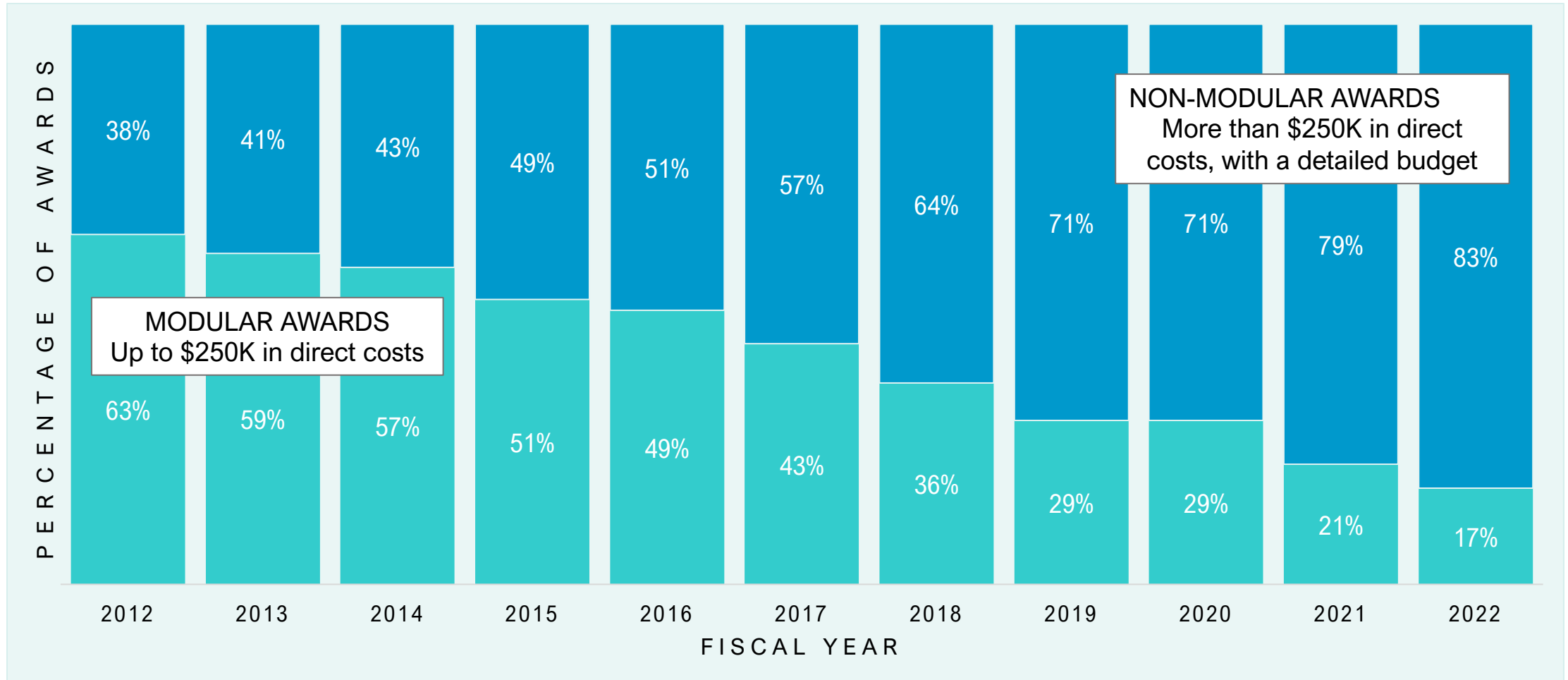


NCI's Research Buying Power is \$1.1B Less than 20 Years Ago

Even with substantial increases in 8 of the last 10 years



Percentage of modular awards has decreased progressively from 63% in 2012 to 17% (~1 in 6 awards) in FY 2022



President's NCI Budget Proposal for Fiscal Year 2024

\$7.8B

Total President's budget proposal for NCI for FY 2024

+ 6.9%

Total NCI budget increase for FY 2024

+ \$500M

Cancer Moonshot increase
(relative to FY 2023 enacted)

+ \$216M

Included for "Year 8" of 21st Century Cures Act (to prevent funding gap/"cliff")

= \$716M

As discretionary resources for Cancer Moonshot (no-year funds)

Budget Outlook (FY24 and FY25)

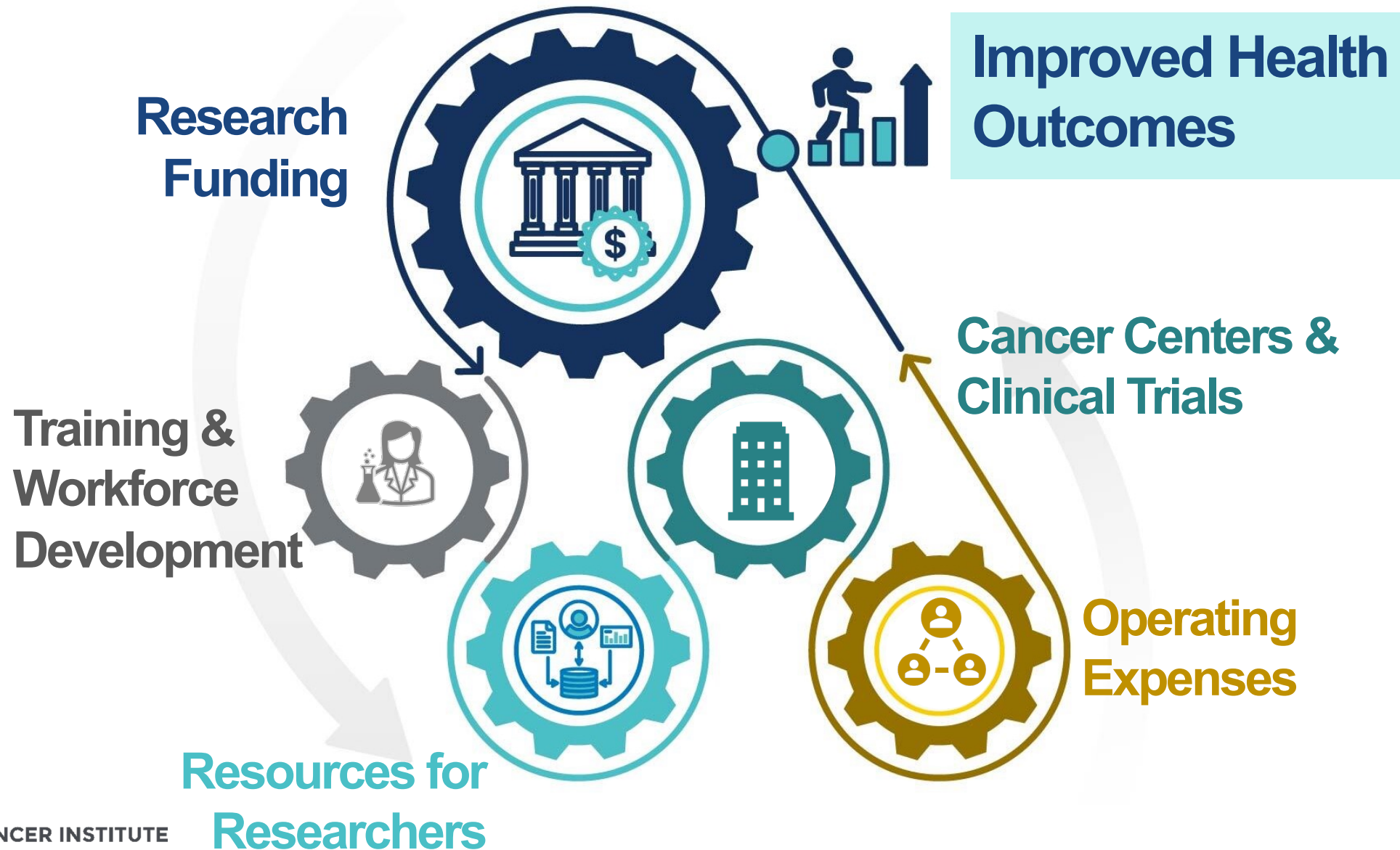
- To meet our goals and narrow gaps in cancer research and care, we need sustained increased funding.
- Although our budget is large, it does not match the opportunities available before us.
- **Bottom line:** NCI's short-term budget outlook is not positive.

	FY 2024	FY 2025
NCI's Professional Judgment Budget Proposal	\$9.988 B	\$11.466 B
President's Budget Proposal for NCI	\$7.8 B (6.9% total NCI budget increase for FY24 compared to FY23 enacted)	<i>The Biden Administration is proposing a further increase of \$1.45 B in mandatory budget authority for both FY25 and FY26</i>
Actual NCI Budget	?	?

Implications of a “flat” FY24 budget

- The “flat” budget may NOT be flat
 - Because the Cancer Moonshot funds were never part of the NCI base budget, the House budget mark for FY24 did not consider the fact that the \$216 million Moonshot funding for FY23 goes to zero in FY24.
 - The Senate mark for FY24 did consider this issue and added the \$216 (plus \$60 million) to its mark
- It is necessary to add ~\$250 million to the RPG pool in FY24 to maintain the current 12th percentile pay line for new awards and fund non-competing awards at 100%
- In addition, NCI incurs \$75-\$100 million each year in increased “mandatory” expenses—Program Evaluation, Cyber Security, Center for Scientific Review

Interconnectedness of NCI budget and program components



All parts of the NCI budget could be adversely affected by a “flat” budget: some examples

- RPG pool: it may be necessary to decrease the “payline” for new awards and fund non-competing awards at substantially lower than 100%
- Cancer Center support grants (CCSGs): It may be necessary to forgo at least some anticipated increases for competing renewals and decrease the amount of non-competing CCSGs
- Cancer training awards: It may be necessary to make fewer new awards
- SPORE grants: It may be necessary to make fewer new awards and reduce the size of non-competing awards
- Intramural research program will be cut at least as much as extramural awards

Some Take-Home Messages

- The need to make progress for our patients, which has always been there, is now being matched by opportunities for meaningful advances.
- However, the anticipated resources for FY24 may not match the opportunities.

We need to *work together* to make progress against cancer as rapidly as possible.

Our patients deserve nothing less.

Thank you!

www.cancer.gov

www.cancer.gov/espanol

1-800-4-CANCER

NCInfo@nih.gov

[@NCIDirector](#)

[@TheNCI](#)



NATIONAL
CANCER
INSTITUTE