

NCI Director's Report

Douglas R. Lowy, M.D.
Acting Director, National Cancer Institute

8th Virtual Joint Meeting of the Board of Scientific Advisors and the National Cancer Advisory Board

November 30, 2023

@NCIDirector
@TheNCI

Today's Talk

- Recent news and updates
- Research and programmatic highlights
- NCI budget outlook
- Discussion

Recent news and updates

NCI Leadership – 2010 to Present



**Harold Varmus,
M.D.**
2010 – 2015



**Ned Sharpless,
M.D.**
2017 – 2022



**Monica Bertagnolli,
M.D.**
2022 – 2023
(Now NIH Director)



**Douglas Lowy, M.D.
(Acting)**
2015 – 2017, 2019,
2022, 2023 (present)



**W. Kimryn Rathmell,
M.D., Ph.D.**
To be appointed

In Memoriam



Wortia McCaskill-Stevens, M.D., M.S.
Director, NCI Community Oncology Research
Program (NCORP)

New Funding Opportunity

**Wortia McCaskill-Stevens
Career Development
Award**

for Community Oncology
and Prevention Research



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?***

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

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

Forbes

What's Next For President Biden's Cancer Moonshot?

Russell Flannery
Sep 21, 2023, 12:45am EDT



In an area of political polarization in Washington, D.C., the Biden administration's Cancer Moonshot has drawn bipartisan support.

**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 components of HHS and NIH

Cancer Survivorship Summit (October 16, 2023)

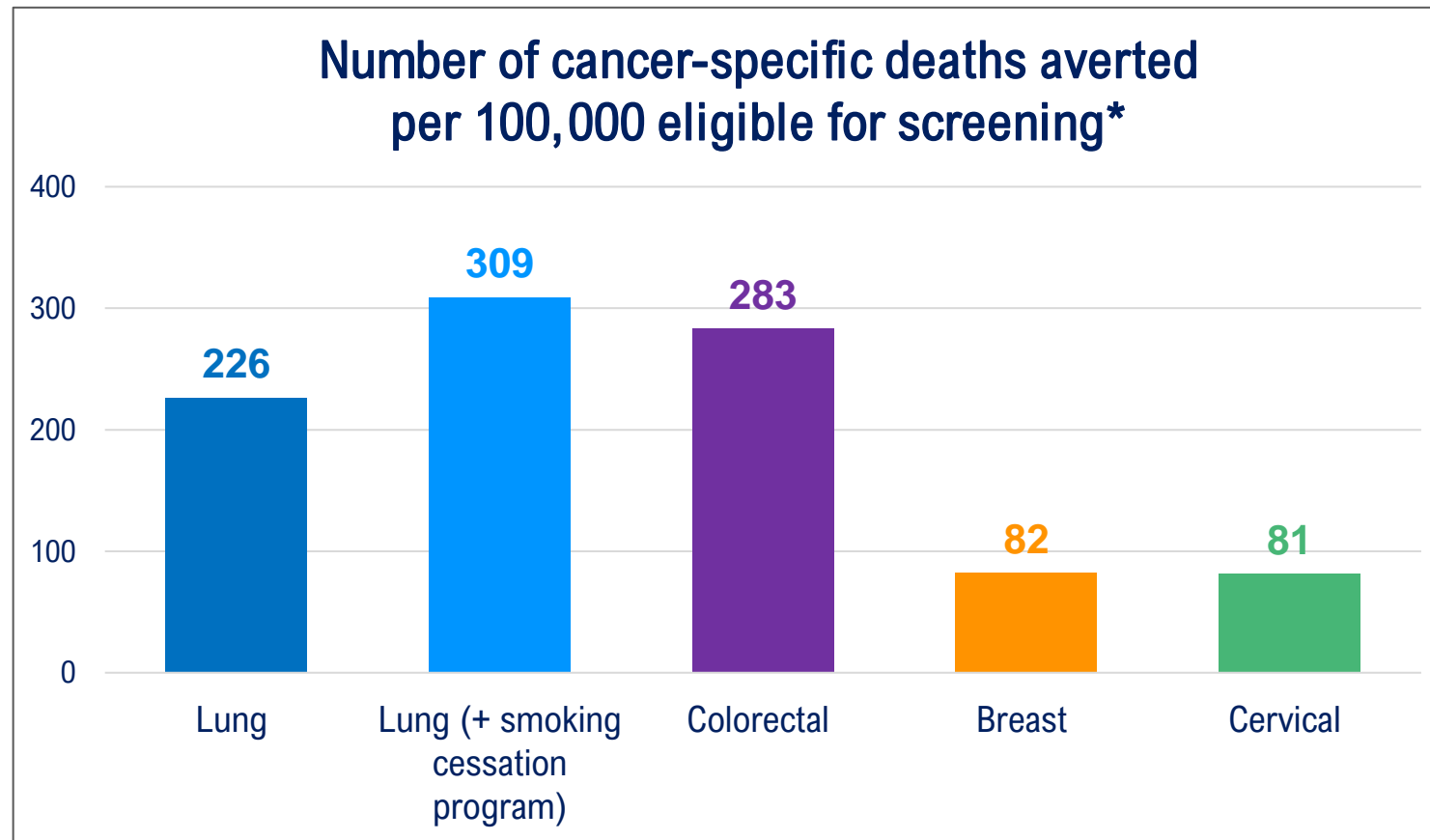
Nova Southeastern University, Davie, Florida

- Speakers/panels highlighted gaps in survivorship care, discussed policy proposals, provided community-based resources and support services
- Hosted by U.S. Representative and survivor of breast cancer Debbie Wasserman Schultz
- Keynote speech: First Lady Dr. Jill Biden
- NCI representation from Dr. Doug Lowy as a guest speaker



Research and programmatic highlights

New analysis: Increasing uptake of recommended screening strategies could reduce cancer burden in U.S.



**Numbers are estimated/modeled based on a 10-percentage point increase in USPSTF recommended screening strategies.*

New paper:

Knudsen A, et al. Estimated US cancer deaths prevented with increased use of lung, colorectal, breast, and cervical cancer screening. *JAMA Network Open*. November 22, 2023.

Eric “Rocky” Feuer, Ph.D. Retirement



CISNET
(Cancer
Intervention and
Surveillance
Modeling
Network)

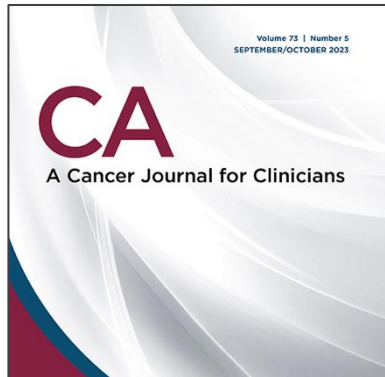
**Incidence-
Based
Mortality**
(can now be
calculated in
SEER*Stat)

DR. FEUER'S CAREER AT NCI — HIGHLIGHTS —

JOINPOINT
software for the
analysis of
trends in cancer
rates

**“Sammies”
Award Nominee**
(Samuel J.
Heyman Service
to America
Medals)

Social Determinants of Health and Cancer Screening



Social determinants of health and US cancer screening interventions: A systematic review

Korn et al. *CA: A Cancer Journal for Clinicians*. June 2023.

Key findings:

- Social determinants of health (SDOH) interventions increased cancer screening* rates by 8.4 percentage points
- Studies that included analyses of health policy, access to care, and lower costs had the most favorable associations with screening outcomes
- SDOH were predominantly measured at the individual level.
 - NIH committee conceptualization: SDOH are structural (not individual) level factors

*breast, cervical, colorectal, and lung



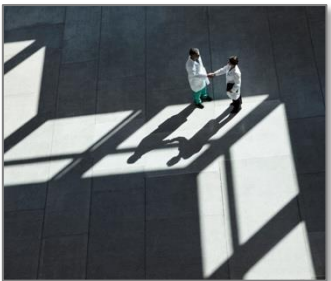
NCI's Cervical Cancer 'Last Mile' Initiative

A public-private partnership bringing together federal agencies, industry, and professional societies to contribute **evidence about the accuracy and clinical effectiveness of self-sampling-based HPV testing for cervical cancer screening.**



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

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

- To evaluate the effectiveness of new blood tests to detect one or more cancer(s) to **prevent cancer-related deaths**

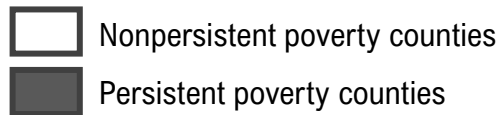
Seven centers will be funded (anticipate announcing in January 2024)



Enduring Disparities in Cancer Mortality by Persistent Poverty, Rurality, and Race

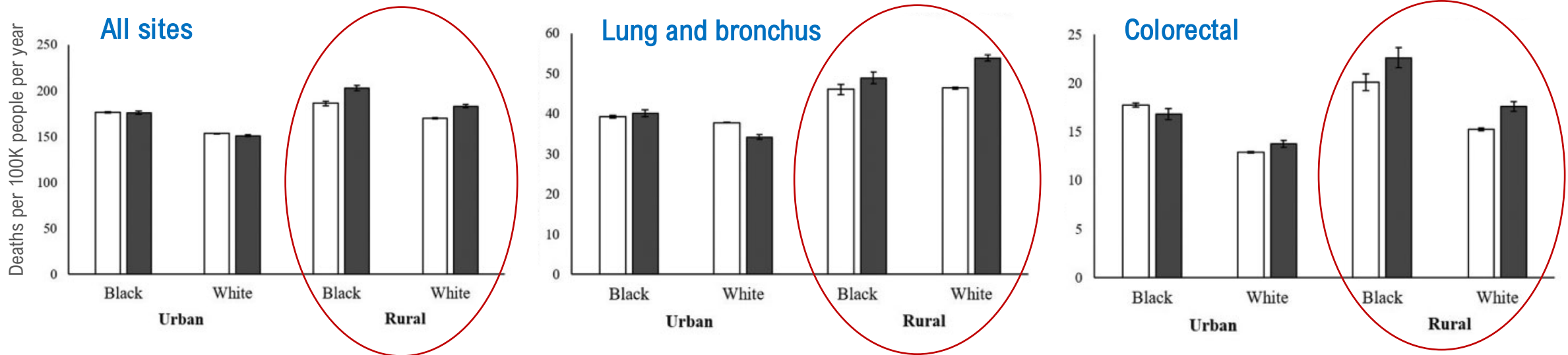
Cancer mortality rates

Deaths per 100,000 people per year

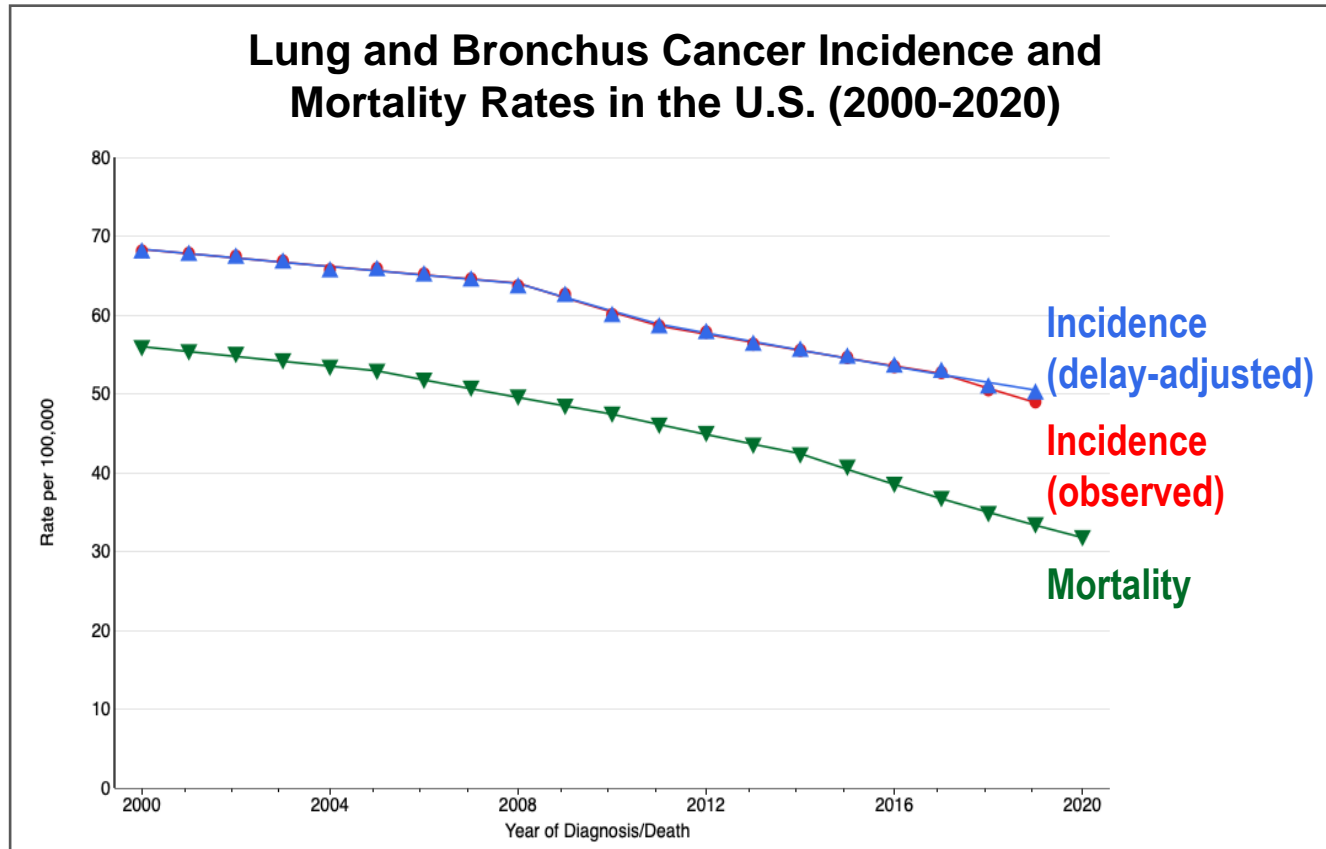


Key conclusions:

- Mortality disparities by persistent poverty endured over time for most cancer outcomes, particularly for racial minorities in rural, persistent poverty counties.
- Multisector interventions are needed to improve cancer outcomes.



Lung Cancer Incidence and Mortality in the U.S.



Annual percent change in:	2000-2008	2008-2011	2011-2019
Incidence rates	-0.8	-2.8	-1.8

Annual percent change in:	2000-2005	2005-2010	2010-2014	2014-2020
Mortality rates	-1.1	-2.2	-2.7	-4.7

- **Improvements in treatment lead to *mortality rates decreasing faster than incidence rates***

Data: seer.cancer.gov



For more: Howlader et al. The Effect of Advances in Lung-Cancer Treatment on Population Mortality. *New England Journal of Medicine*. August 13, 2020.

Improvements in treatment are contributing to declining lung cancer mortality rates

Recent FDA approvals (August 2022 – present)

Date,	Approval / Treatment
11/15/2023	Repotrectinib for ROS1-positive NSCLC
10/16/2023	Neoadjuvant/adjuvant pembrolizumab for resectable NSCLC
10/11/2023	Encorafenib with binimetinib for metastatic NSCLC with a BRAF V600E mutation
8/9/2023	Pralsetinib for NSCLC with RET gene fusions
1/26/2023	Pembrolizumab as adjuvant treatment for NSCLC
12/12/2022	Adagrasib for KRAS G12C-mutated NSCLC (accelerated approval)
11/10/2022	Tremelimumab with durvalumab and platinum-based chemotherapy for metastatic NSCLC
11/8/2022	Cemiplimab-rwlc in combination with platinum-based chemotherapy for NSCLC
9/21/2022	Selpercatinib for locally advanced or metastatic RET fusion-positive NSCLC
8/11/2022	Fam-trastuzumab deruxtecan-nxki for HER2-mutant NSCLC (accelerated approval)
8/10/2022	Capmatinib for metastatic NSCLC

NCI supports basic and clinical research that lead to development of effective treatments and approvals

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

For more information, see:

“Collaborative Approaches to Accelerate Better Therapies for Patients with Rare Tumors”

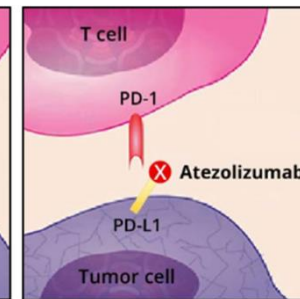
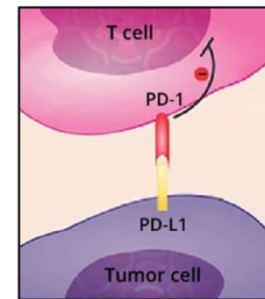
Sept. 2023 NCAB meeting

<https://deainfo.nci.nih.gov/advisory/ncab/0923/Widemann-Reilly.pdf>

- Focusing on rare solid tumors affecting **children, teens, and young adults (<39)**
- Engaging patients, family members, advocates, clinicians, scientists, as **partners in research**
- Hosting **multi-day clinics** for rare tumors to bring patients and nationwide experts together
- Collecting longitudinal **molecular, clinical, and patient reported** outcome data through the **Natural History Study of Rare Solid Tumors (NCT03739827)**

PD-L1 immune checkpoint inhibitor (Atezolizumab) approval for advanced alveolar soft part sarcoma; led by NCI intramural program

- An NCI-led clinical trial resulted in the **first approval of a treatment for advanced alveolar soft part sarcoma (ASPS)**, an extremely rare cancer that affects mostly adolescents and young adults
- First time atezolizumab has been approved for children
- Largest study on ASPS
- Previously approved for treating several other cancer types, including liver cancer, melanoma, lung cancer



Atezolizumab binds to PD-L1 and blocks it from binding to another checkpoint protein, PD-1.

“Forty percent of the patients were treated at the NIH Clinical Center in Bethesda. Our ability to bring patients in from all over the world was a key factor in the ability to do the study.”

*– James Doroshov, M.D.,
NCI Deputy Director for Clinical and Translational Research*



Chen et al. Atezolizumab for Advanced Alveolar Soft Part Sarcoma. *NEJM*. September 7, 2023.

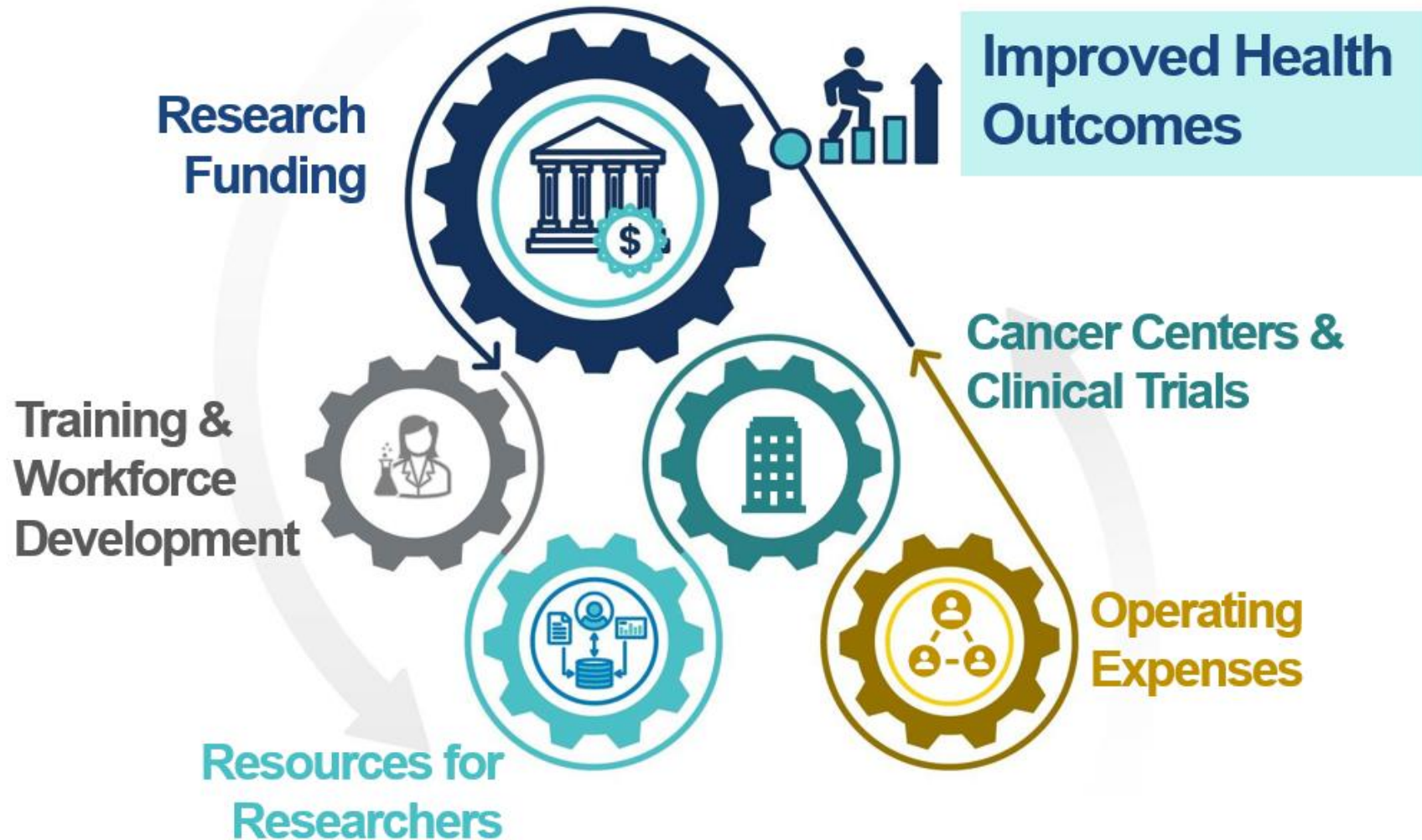
Budget outlook

NCI Budget & Paylines – 2017 - 2023

	FY 2017	FY 2023	FY 2024
NCI Total Appropriation in millions	\$5,689	\$7,320	?
Cancer Moonshot SM (included in total)	\$300M	\$216M	?

	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
R01 Payline Percentile (Established Investigators)	10	9	8	10	11	11	12
R01 Payline Percentile (Early Stage Investigators)	12	14	14	15	16	16	17

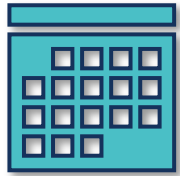
Interconnectedness of NCI budget and program components



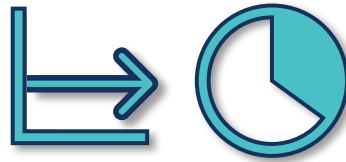
**NCI's budget
is determined
within the
federal budget
ecosystem**
alongside many other
national priorities



Where we are today



Potential lapses
in appropriation
averted:
September 30,
November 17



Current Continuing
Resolution expires
February 2
(one-third into the
fiscal year)



Interim paylines
have been set.
Will not be adjusted
until NCI receives a
full-year
appropriation.

FY24 Interim Paylines Announced

FY24 Interim Paylines for NCI Competing Grants Effective November 2, 2023	
Grant Type	Interim Payline
R01 Grants for Established & New Investigators	9th Percentile
R01 Grants for Early-Stage Investigators	14th Percentile
R21 Exploratory Grants	9th Percentile
<i>NCI will generally fund noncompeting grants at 90% of the committed level.</i>	



Budget Outlook: FY24 and FY25

	NCI's Professional Judgment Budget Proposal	President's Budget Proposal for NCI	Actual NCI Budget
FY 2024	\$9.988B	\$7.8B <ul style="list-style-type: none"> 6.9% total NCI budget increase for FY24 compared to FY23 enacted Includes \$216M for Cancer Moonshot 	?
FY 2025	\$11.466B	?	?



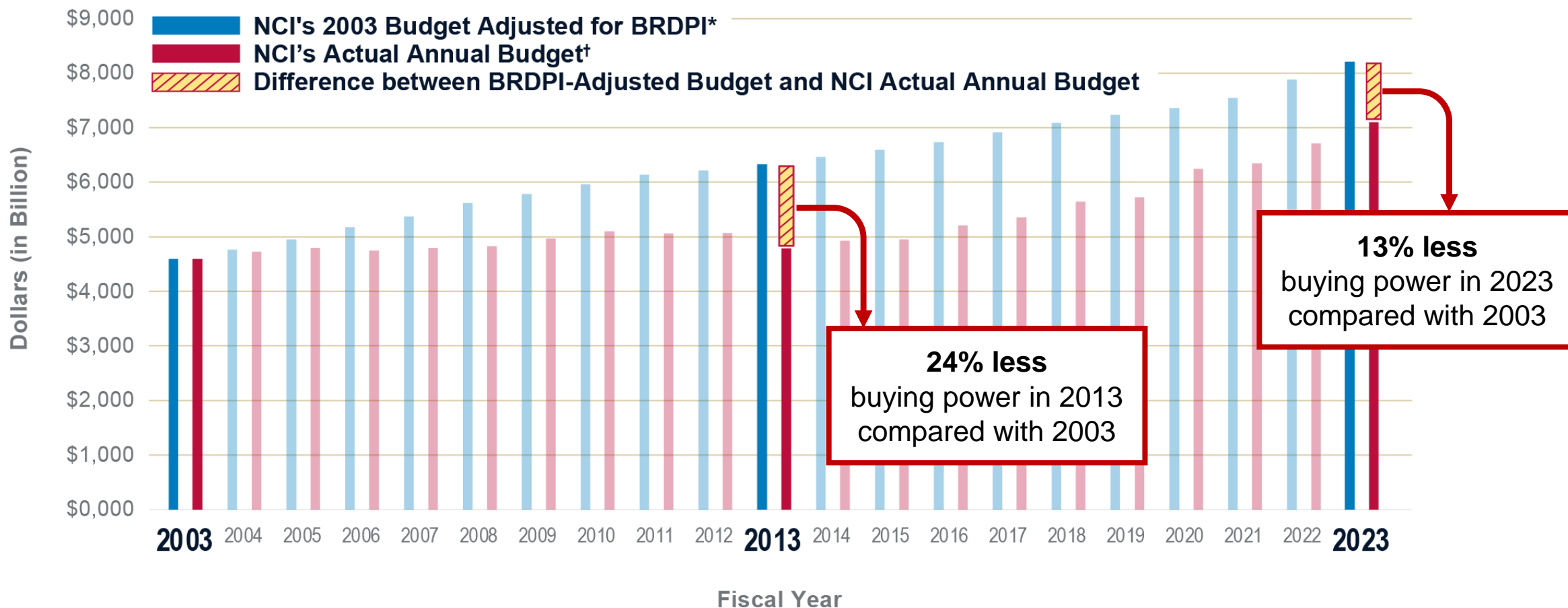
To maintain the FY 2023 payline (12th percentile) and fund continuing grants at 100%, NCI needs to add **\$250M** to the RPG pool.



NCI incurs **\$75-\$100M** each year in increased “mandatory” expenses *E.g., physical and cyber security, utilities, Center for Scientific Review, etc.*

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

Even with substantial increases in 8 of the last 10 years



Consider: A \$10B budget in FY24 would be +18% more buying power than FY03, or less than 1% increase in buying power per year since FY 2003

A “flat” budget is not truly flat

- Research costs continue to increase
- FY 2023 was the last year of 21st Century Cures Act funding for the Cancer MoonshotSM
- Non-negotiable expenses for NCI increase each year by \$75-100M

May necessitate cuts across NCI programs – for example:

RPG Pool

- Decrease the “payline” for new awards
- Fund non-competing awards at lower than 100%

Cancer Center Support Grants (CCSGs)

- Forgo at least some anticipated increases for competing renewals
- Decrease the amount of non-competing CCSGs

Cancer Training Awards

- Make fewer new awards

SPORE Grants

- Make fewer new awards
- Reduce the size of non-competing awards

Intramural Research Program

- Cut at least as much as extramural awards

Resources about NCI Budget and Appropriations



Sept. 6 NCAB: NCI budget overview
www.videocast.nih.gov/watch=52268&start=3723

NCI's Fiscal Year 2024 Budget Challenges and Interim Paylines Explained

Subscribe

November 15, 2023, by NCI Acting Director, Dr. Douglas R. Lowy

UPDATE: Since this blog was posted on November 15, Congress passed another short-term continuing resolution that extends funding for the National Institutes of Health at last fiscal year's budget levels through February 2, 2024. In this post, NCI Acting Director Dr. Lowy describes key challenges that this "flat" budget presents to NCI and its effects on NCI's ability to support cancer research. He also discusses newly announced interim paylines for competing grants.



NCI *Bottom Line* blog post on FY24 budget outlook:
www.cancer.gov/grants-training/nci-bottom-line-blog/



Updated budget and appropriations page:
www.cancer.gov/about-nci/budget



NCI Fiscal Year 2025
Professional Judgment Budget Proposal:
www.cancer.gov/research/leading-progress

Thank you!

www.cancer.gov

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