

NCI Director's Report

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Director, National Cancer Institute

June 14, 2023

*15th Joint Meeting of the Board of Scientific Advisors
and the National Cancer Advisory Board*

@NCIDirector
@TheNCI

Welcome!

National Cancer Advisory Board (NCAB)

Margaret Anne Anderson

Deloitte Consulting LLP

Richard J. Boxer, MD

University of California, Los Angeles

Ysabel Duron

The Latino Cancer Institute

Julie Papanek Grant, MBA

Canann

Ana Navas-Acien, MD, PhD, MPH

Columbia University

Fred K. Tabung, PhD, MSPH

The Ohio State University

Today's Talk

- NCI News and Events
- Budget/Paylines
- Cancer Drug Shortages
- National Cancer Plan Updates
- NCI Program Updates
- Research Advances

Recent White House Cancer Moonshot events

Cancer Moonshot **Smoking Cessation Forum**

June 1, 2023

Cancer Moonshot **Brain Cancers Forum**

May 25, 2023

Cancer Moonshot **Colorectal Cancer Forum**

March 10, 2023



American Society of Clinical Oncology (ASCO)

June 2-6, 2023

Major NCI DCTD/CTEP-supported trials presented at ASCO 2023:

PROSPECT (Alliance N1048): Randomized phase III trial of neoadjuvant chemoradiation versus neoadjuvant FOLFOX chemotherapy with selective use of chemoradiation, followed by total mesorectal excision for treatment of locally advanced rectal cancer

COG ADVL1823 Cohort A: Phase II study of larotrectinib in children with newly diagnosed infantile fibrosarcoma

SWOG S1826: Randomized study of nivolumab-AVD versus brentuximab vedotin-AVD in advanced stage classic Hodgkin lymphoma

SWOG S1011: Phase III surgical trial to evaluate the benefit of a standard versus an extended lymphadenectomy performed at time of radical cystectomy for muscle invasive urothelial cancer

NCI-COG Pediatric MATCH Trial Arm I (APEC1621I): Palbociclib in solid tumor patients with genomic alterations in the cyclin D-CDK4/6-INK4a-Rb pathway

Alliance A091902: A multicenter phase II study of cabozantinib + nivolumab for patients with advanced angiosarcoma previously treated with a taxane

NCI-COG Pediatric MATCH Trial Arm B (APEC1621B): Erdafitinib in patients with FGFR-altered tumors

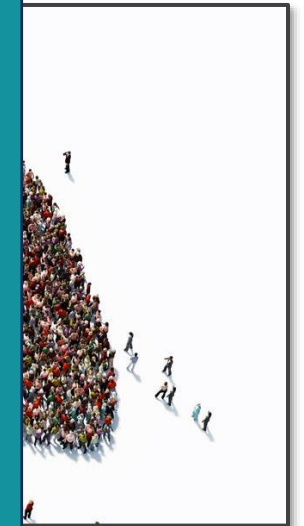
Pragmatica-Lung Study (S2302)

A streamlined model for future cancer clinical trials

Designed to

- Eliminate
- Increase
- Streamline
execution
- Use for
collecti
- Complete

Concept presentation to first patient accrual:
August 2022 – March 2023



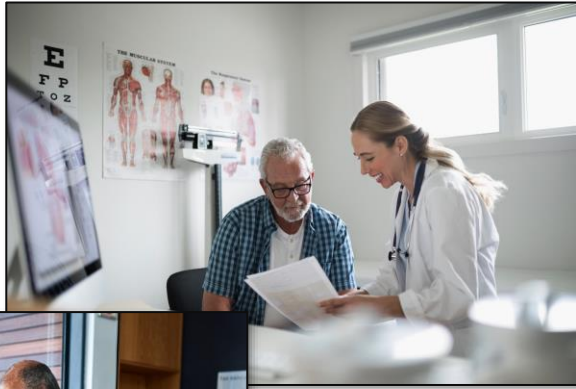
*Led by SWOG Cancer Research Network, in collaboration
with the Alliance for Clinical Trials in Oncology*



*Purpose: Evaluate whether
ramucirumab + pembrolizumab
combination therapy improves
overall survival over standard
treatment in people with
advanced NSCLC.*

Clinical Trials Innovation Unit (CTIU):

Better, faster, more accessible cancer clinical trials



The CTIU will:

- **Select a few high-priority studies** for new study designs and operational procedures
- **Help speed clinical testing to deliver new approaches** for diagnosis, treatment, and prevention of cancer
- **Accept inputs** from the extramural research community
 - ✓ First proposal submission deadline: June 12

A collaboration between NCI, the FDA Oncology Center of Excellence, and the NCTN Group Chairs

Examples of NCI's Contributions to Our Shared Goals



- Pragmatica-Lung Study (S2302)
- Clinical Trials Innovation Unit (CTIU)

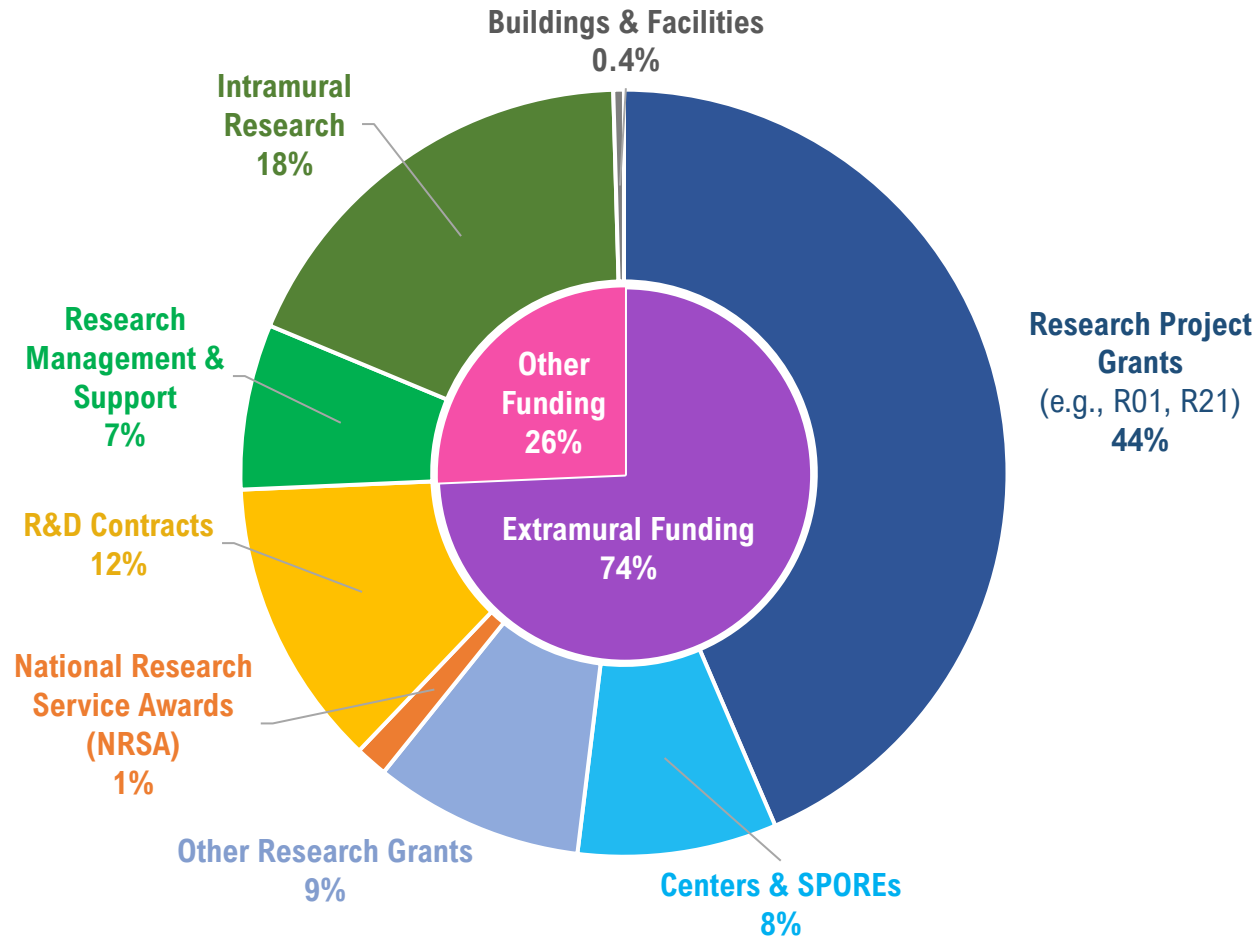


- Connecting Underrepresented Populations to Clinical Trials (CUSP2CT)
- Telehealth Research Centers of Excellence (TRACE)



- Childhood Cancer–Data Integration for Research, Education, Care, and Clinical Trials (CC-DIRECT)
- NCI Community Oncology Research Program (NCORP)

How does NCI spend its money?



Examples of mechanisms:

Centers and SPOREs

- Cancer Center Grants (P20/P30), SPOREs, other P50s/P20s, other Specialized Centers

Other Research Grants

- Career Programs (K Awards), Cancer Education, Clinical Cooperative Groups, Pre-Doc Post-Doc Transition Awards, Education Projects - Cooperative Agreements, Minority Biomedical Research Support, Research Pathway in Residency, Pilot Research Project, Resource Grants, International Research Training grants, Cooperative Conference Agreements, Conference grants, and Other Transaction Authority

NRSA

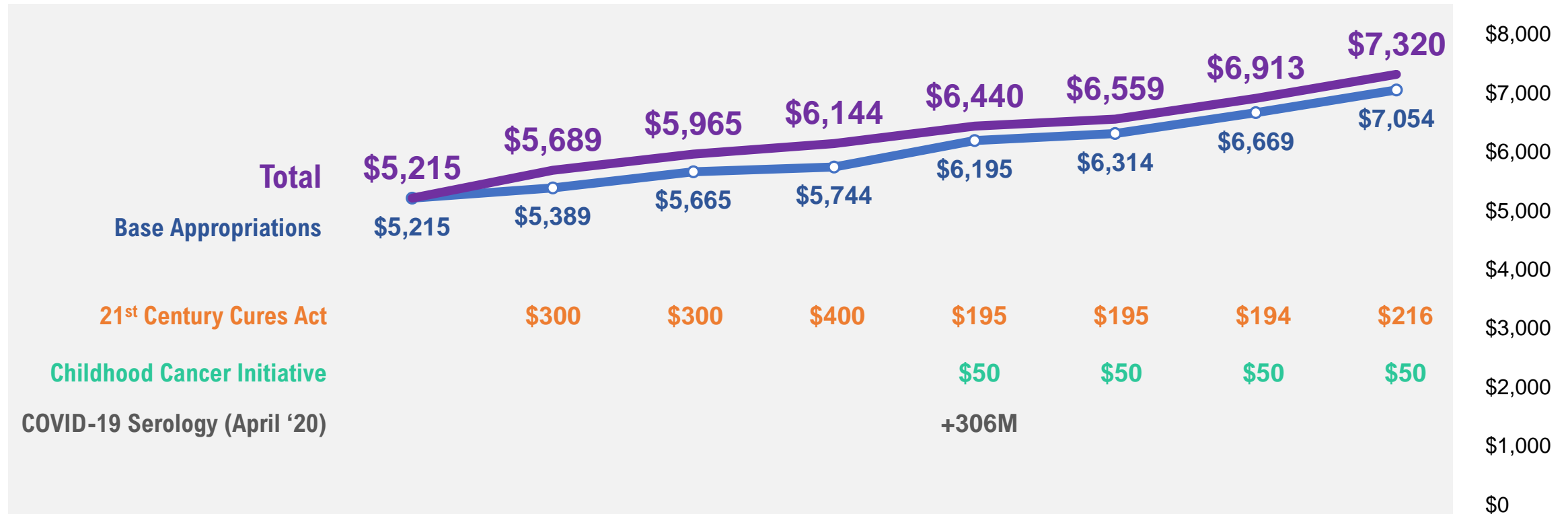
- Ruth L. Kirschstein NRSA Institutional Research Training Grant (T32)

R&D Contracts

- Frederick National Lab, SBIR contracts

NCI Appropriations and Paylines (FY 2016 – 2023)

Dollars in millions

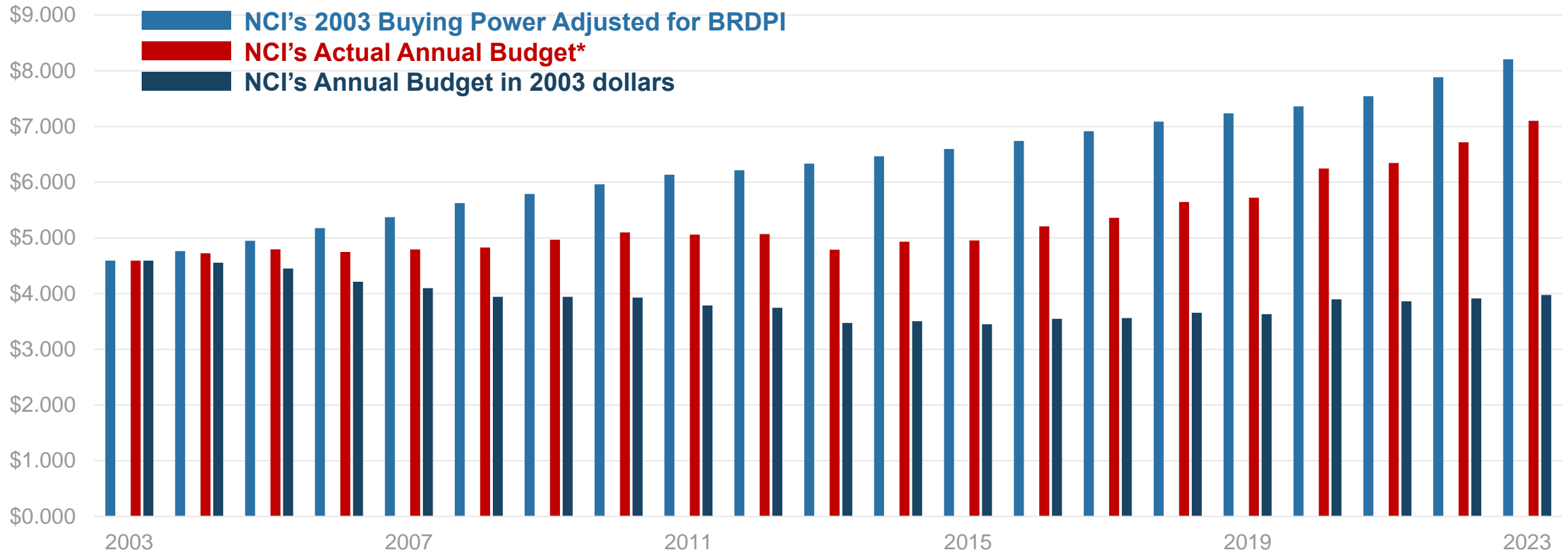


		FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
Paylines* (percentile)	Established	10	10	9	8	10	11	11	12
	Early-Stage	12	12	14	14	15	16	16	17

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

NCI's Budget Over Time

How does the 2023 NCI budget compare to 2003?



NCI's Purchasing Power

Biomedical Research and Development Price Index (BRDPI)

BRDPI measures the changes in prices of all the inputs purchased with the NIH budget to support research.

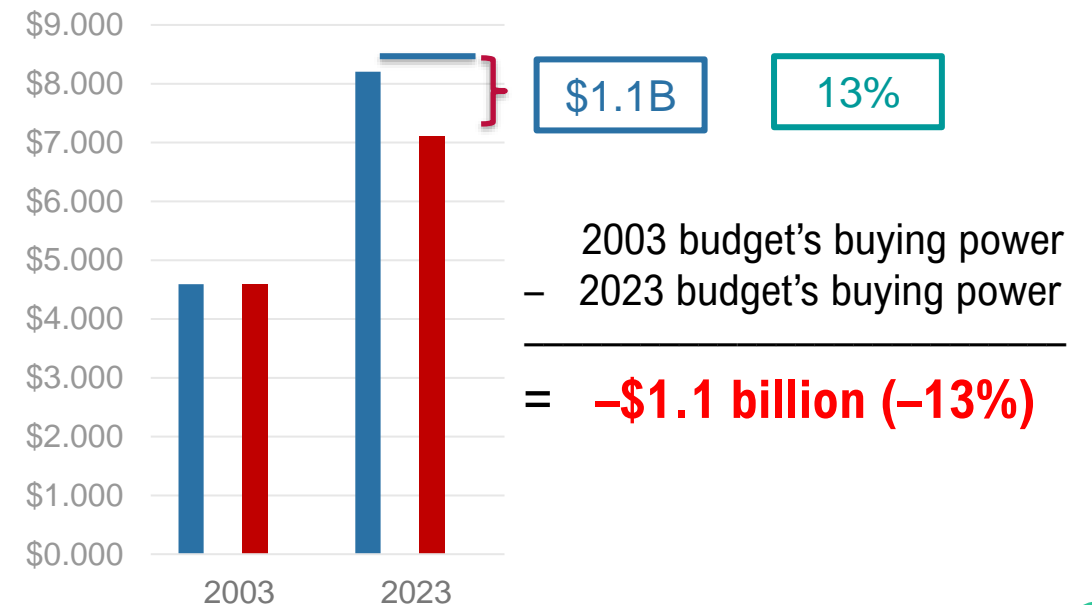
Cumulative annual change in the BRDPI
(e.g., 13%)

=

How much NIH budget must change to maintain purchasing power parity
(i.e., previous year's activities)

Implications:

- NCI can afford 13% less than 20 years ago
- NCI is \$1.1 billion below keeping up with inflation costs



Cancer Drug Shortages

**Oncology agents
currently listed in
FDA's Drug Shortages
Database:**

- **Azacytidine** for Injection
- **Capecitabine** Tablets
- **Carboplatin** Injection
- **Cisplatin** Injection
- **Cytarabine** Injection
- **Dacarbazine** Injection
- **Fludarabine Phosphate** Injection
- **Leucovorin Calcium** Lyophilized Powder for Injection
- **Methotrexate** Injection

Estimated number of trials* with oncology agents currently in short supply

Current Trial Status	ETCTN	NCTN	Consortia (AMC, PBTC, CITN, PEP-CTN)	CCR	Formulary	Old N01 ETCTN	NHLBI	Grand Total
Active	12	69	2	1	0	0	1	85
Temporarily Closed to Accrual	2	11	3	0	0	0	0	16
Closed to Accrual	2	38	0	0	0	3	0	4
Approved	0	4	0	0	0	0	0	4
Approval on Hold	2	9	0	0	1	0	0	12
In Review	1	9	0	0	0	0	0	10
Grand Total	19	140	5	1	1	3	1	170

**Trials supported/sponsored by NCI's Cancer Therapy Evaluation Program (CTEP)*

Data updated as of May 22, 2023

Data courtesy of James H. Doroshow, MD (NCI Deputy Director for Clinical and Translational Research)

Estimated number of studies with shortage list oncology agents on protocol

No. of shortage list agents on protocol	No. of Studies
One (1) shortage agent on protocol	104
Two (2) shortage agents on protocol	47
Three (3) shortage agents on protocol	16
Four (4) shortage agents on protocol	3
Grand Total	170

**Trials supported/sponsored by NCI's Cancer Therapy Evaluation Program*

Data updated as of May 22, 2023

Data courtesy of James H. Doroshow, MD, NCI Deputy Director for Clinical and Translational Research

National Cancer Plan

NationalCancerPlan.cancer.gov

National Cancer Plan



Everyone has a role.

April 3, 2023

U.S. Department of Health & Human Services | National Institutes of Health | National Cancer Institute

National Cancer Plan

Sign up for the new
National Cancer Plan
newsletter



Use the
National Cancer Plan
Digital Toolkit



Visit:
NationalCancerPlan.
cancer.gov



National Cancer Plan

Implementation

Leadership from the President's Cancer Panel

- Engaging the community in public sessions
 - Showcase contributions
 - Demonstrate progress to public
- Tracking progress over time
 - Annual reporting
 - In-depth progress reviews for two goals per year
 - ✓ 4-year cycle for in-depth review of all goals
 - ✓ Review article published in a peer-reviewed journal

National Cancer Plan Updates
June 2023

National Cancer Plan: Eight Goals, One Mission

Welcome to the first issue of *National Cancer Plan Updates*. This newsletter, from the National Cancer Institute and the [President's Cancer Panel](#), delivered directly to your inbox, provides important information on the cancer community's efforts to end cancer as we know it through implementation of a new U.S. National Cancer Plan.

Released in April, the [National Cancer Plan](#) is a long-term, ambitious framework that outlines eight goals intended to prevent cancer, reduce cancer-related deaths, and improve the lives of individuals affected by cancer.

EIGHT GOALS

- ➕ Prevent Cancer
- 🔍 Detect Cancers
- 📄 Develop Effective Treatments
- ⚖️ Eliminate Inequities
- ❤️ Deliver Optimal Care
- 👤 Engage Every Person
- 📊 Maximize Data
- 🧠 Optimize the Workforce

The plan provides a road map for meeting the Cancer Moonshot: to reduce the cancer death rate by 50% by 2035.

In future updates, look for:

- Spotlights on the cancer community's efforts
- Focus on progress being made and when the eight goals
- Social media engagement around the plan

NEWS AND EVENTS

In the News and Social Media

Since its release, various media

Instagram

- Use and customize the following post: Imagine a world without cancer. What does it mean to you? The #NationalCancerPlan is a framework that promotes collaboration among all-of society to end cancer as we know it today. Explore the plan's eight goals – you're just one link in bio click away. #Every1HasARole #CancerMoonshot #CancerResearch #CancerTreatment #HealthyPeople #CancerDiagnosis #CancerPrevention #HealthEquity
- Amplify NCI's [Instagram post](#).

Social Media Graphics

Newsletter, June 2023

Digital Toolkit sample assets

ComboMATCH: Combination Therapy Platform Trial with Molecular Analysis for Therapy Choice

Trials open for enrollment	
<i>Combination therapy trial</i>	<i>Patients matched to trial</i>
Fulvestrant (Faslodex) and binimetinib (Mektovi)	Patients with an NF1 mutation in hormone receptor-positive breast cancer that has spread
Selumetinib (Koselugo) and olaparib (Lynparza) or selumetinib alone	Women with a RAS mutation who have endometrial or ovarian cancer that has come back or persists despite treatment
Chemotherapy plus ipatasertib	Patients with AKT mutations who have solid tumors that have spread

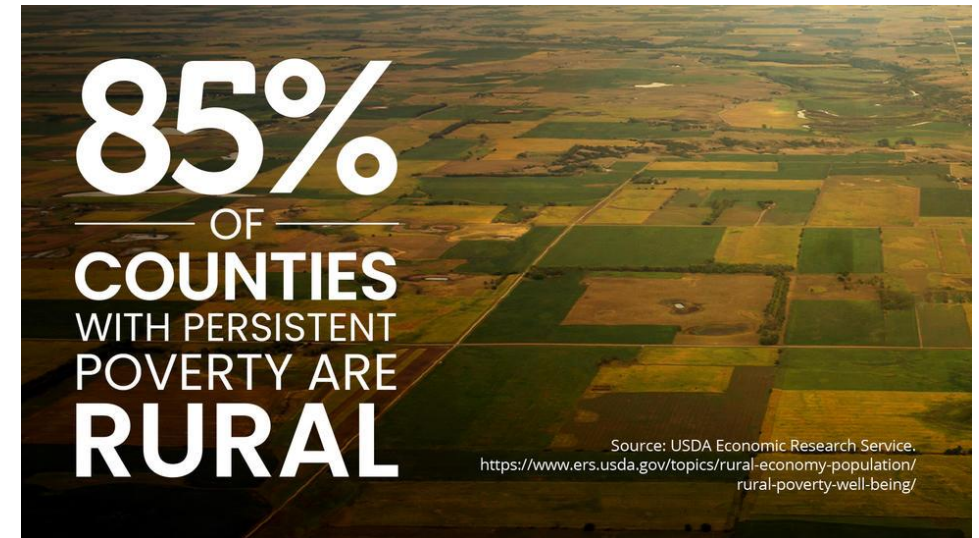


Plans:

- *6 trials to be available in coming months (more over time)*
- *Include ~2,000 patients*

Persistent Poverty Initiative

- \$50 million to improve cancer outcomes in low-income areas by:
 - Building research capacity
 - Fostering cancer prevention research
 - Promoting the implementation of community-based programs
- Awards will fund **5 new Centers for Cancer Control Research in Persistent Poverty Areas** (\$10 million over 5 years)
- First major program to address the structural and institutional factors of persistent poverty in the context of cancer



Recent Research Advances



Personalized PSA levels could improve prostate cancer screening

Kachuri et al. Genetically adjusted PSA levels for prostate cancer screening. *Nature Medicine*. June 1, 2023.



Less than 7% of patients newly diagnosed with cancer are tested for germline genetic mutations

Kurian et al. Germline Genetic Testing After Cancer Diagnosis. *JAMA*. June 5, 2023.



3-in-1 approach helps women in rural areas get cancer screenings

Champion et al. Comparative Effectiveness of 2 Interventions to Increase Breast, Cervical, and Colorectal Cancer Screening Among Women in the Rural USA: Randomized Clinical Trial. *JAMA Network Open*. April 23, 2023.

RNA-based Cancer Vaccines

Request for Information

Responses will be used to inform future resource allocation and acquisition strategies that can accelerate the development, availability, and evaluation of such agents.

Send responses and questions to Dr. Andrew Kurtz at nciRNAvaccines@mail.nih.gov



NOTICE NUMBER:
NOT-CA-23-063

**Needs and Challenges in
Obtaining and Testing
Clinical-Grade RNA-based
Cancer Vaccine Formulations
to Support Translational and
Clinical Research**

Responses due by June 30, 2023

Thank you!

www.cancer.gov

www.cancer.gov/espanol

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