NCI Director's Update

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Director, National Cancer Institute

July 19, 2023

51st Meeting of the Clinical Trials and Translational Research Advisory Committee (CTAC)

@NCIDirector
@TheNCI

NIH NATIONAL CANCER INSTITUTE

Today's Talk

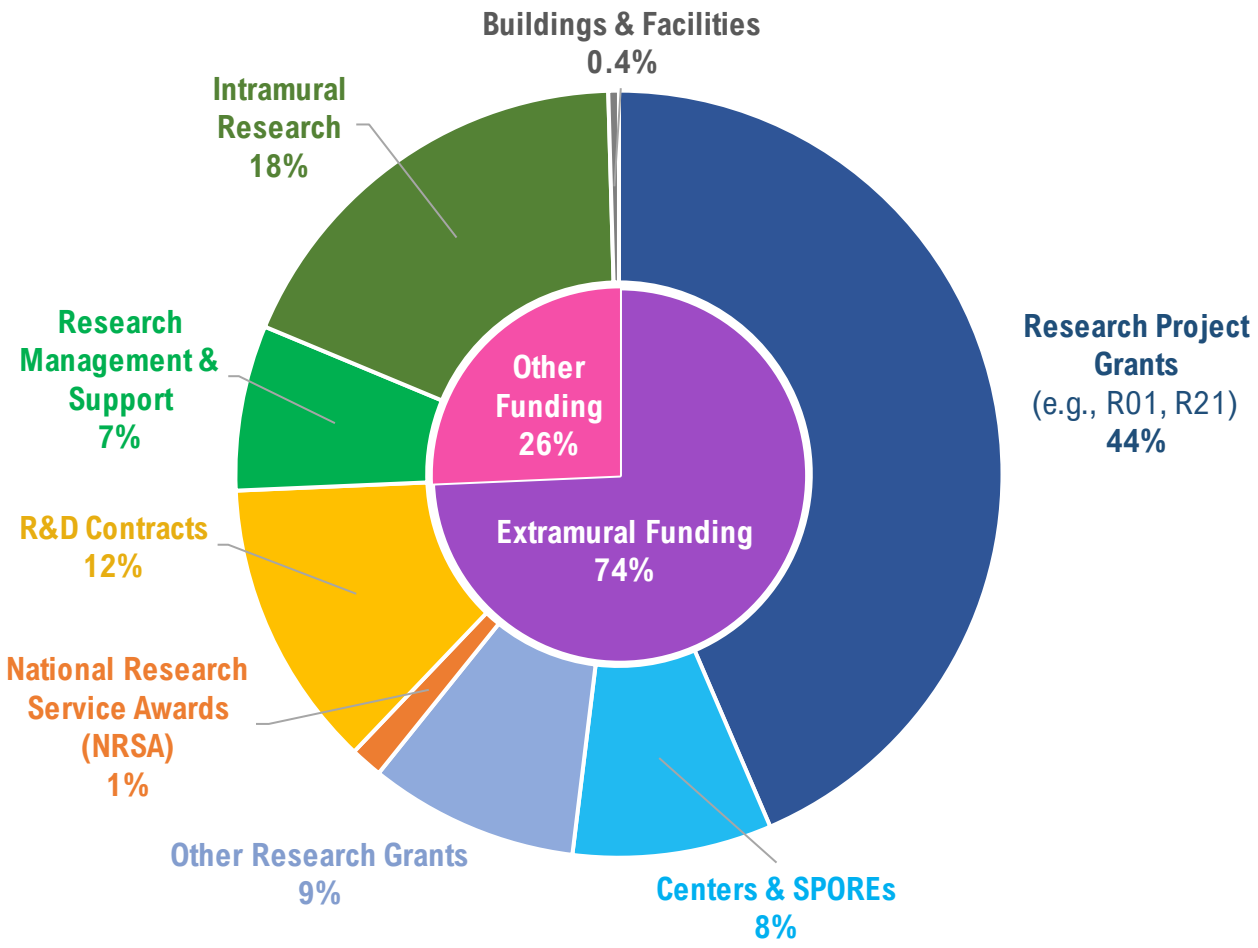
- NCI News/Events
- Budget/Paylines
- Cancer Drug Shortages
- National Cancer Plan
- NCI Program Updates

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): Erdafitinb in patients with FGFR-altered tumors	

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

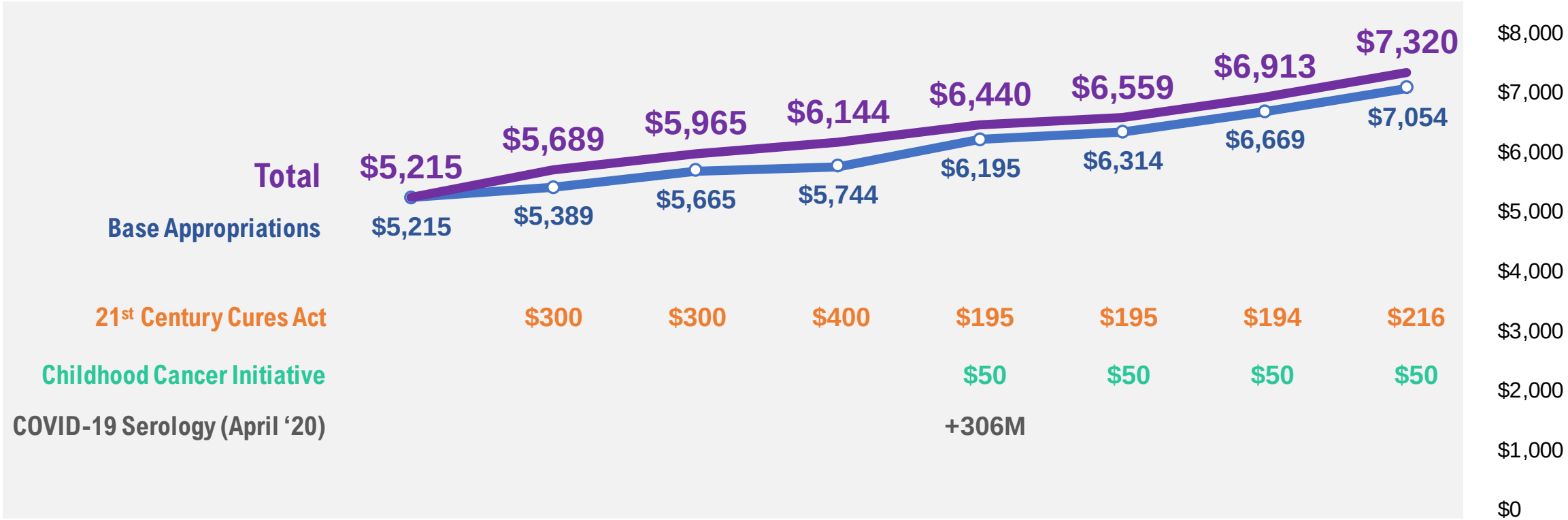
- Ruth L. Kirschstein NRSA Institutional Research Training Grant (T32)

R&D Contracts

- Frederick National Lab, SBIR contracts, Surveillance, Epidemiology, and End Results (SEER) Program

NCI Appropriations and Paylines (FY 2016 – 2023)

Dollars in millions



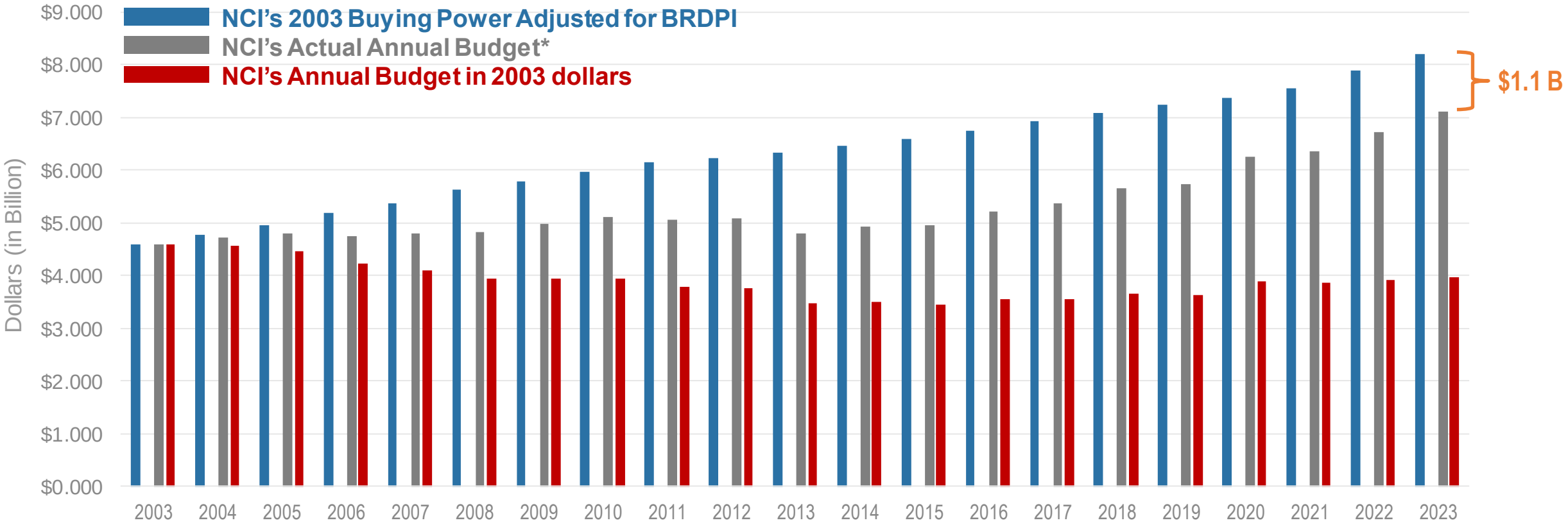
		FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
Paylines* (percentile)	**Established**	10	10	9	8	10	11	11	12
	Early-Stage	12	12	14	14	15	16	16	17

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

NCI's Budget, 2003 - 2023

Key points:

- 2023 purchasing power is **$1.1 B lower** than in 2003.
- NCI can **afford 13% less** than 20 years ago.



Content courtesy of Weston Ricks, Office of Budget and Finance, NCI
**Post transfers, excludes ARRA, 21st Century Cures Act funding, etc.*

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

Data updated as of May 22, 2023

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

Cancer Drug Shortages

Estimated number of trials* with oncology agents in short supply (listed in FDA's Drug Shortages Database):

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 courtesy of James H. Doroshow, MD (NCI Deputy Director for Clinical and Translational Research)
Data updated as of May 22, 2023

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

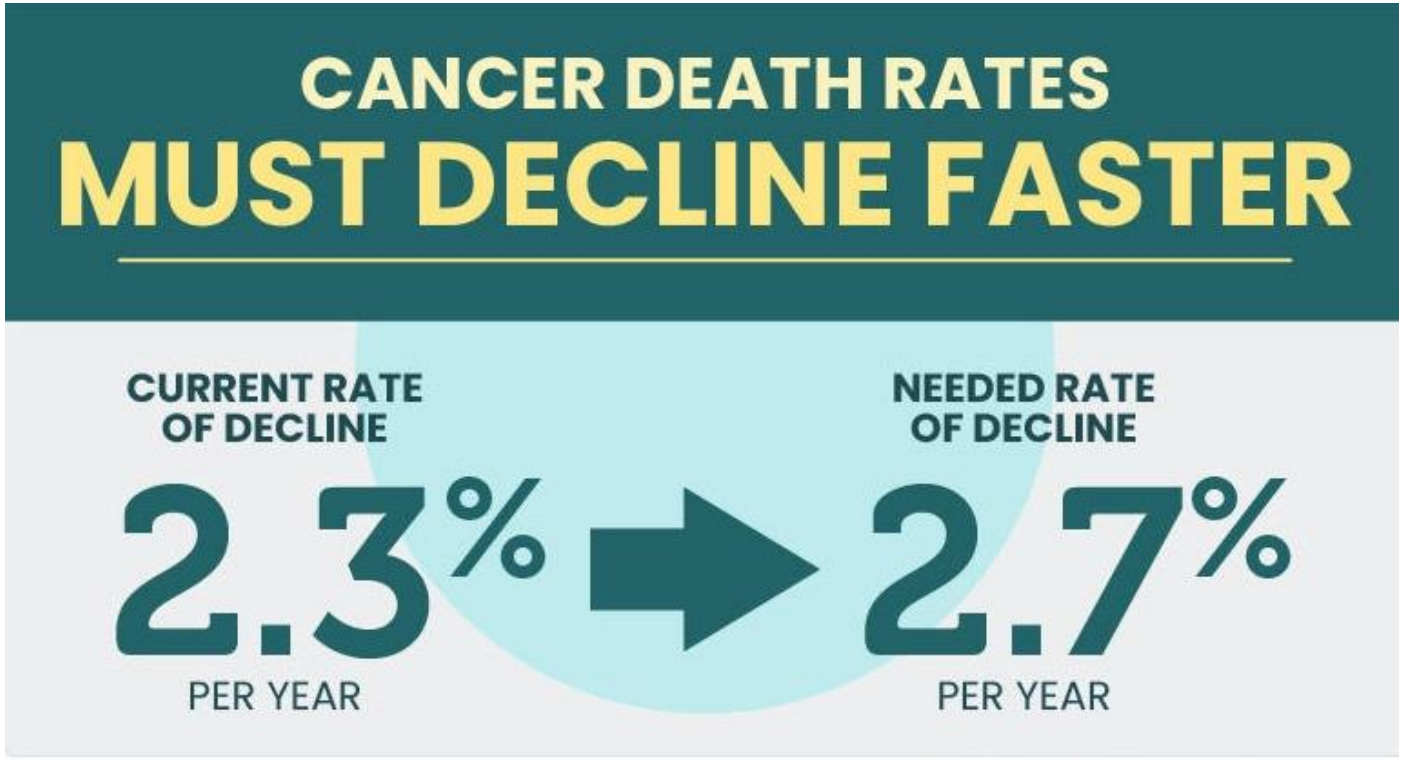
Achieving the Cancer Moonshot Goals

REDUCE CANCER MORTALITY BY AT LEAST

50%

over the next 25 years

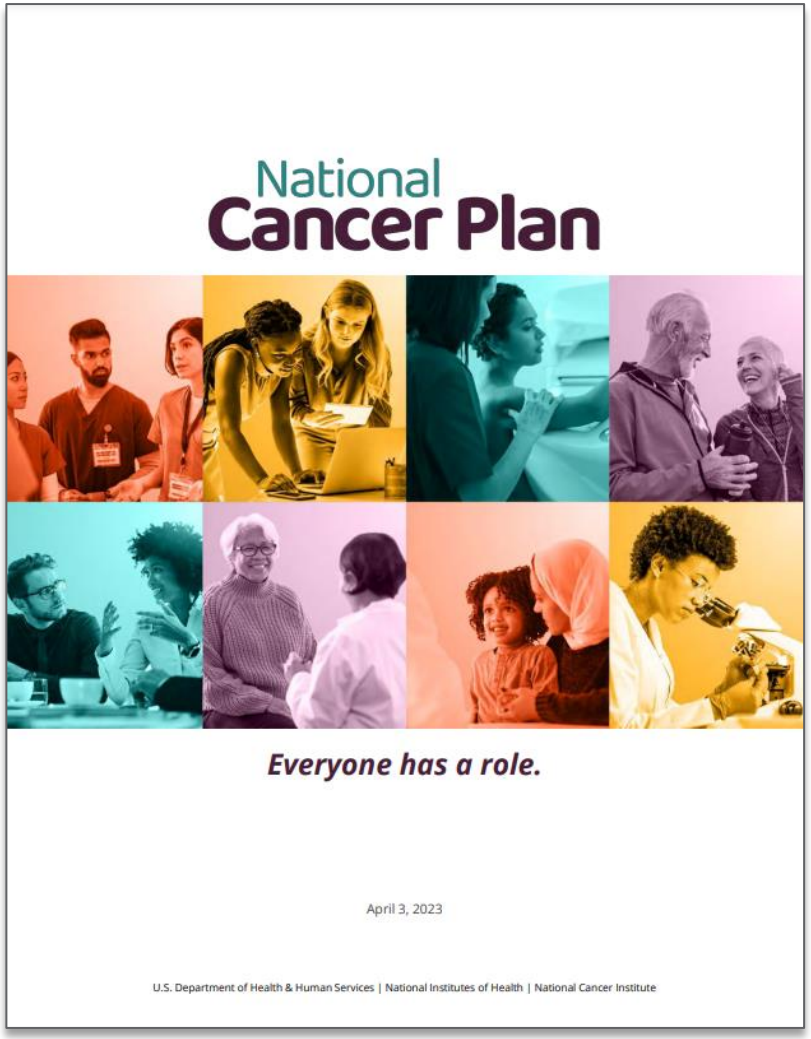
and improve the experience of people and their families living with and surviving cancer.



SOURCE: Shiels M, et al. *Cancer Discovery*. 2023

National Cancer Plan

NationalCancerPlan.cancer.gov



GOALS What success looks like

NationalCancerPlan.cancer.gov

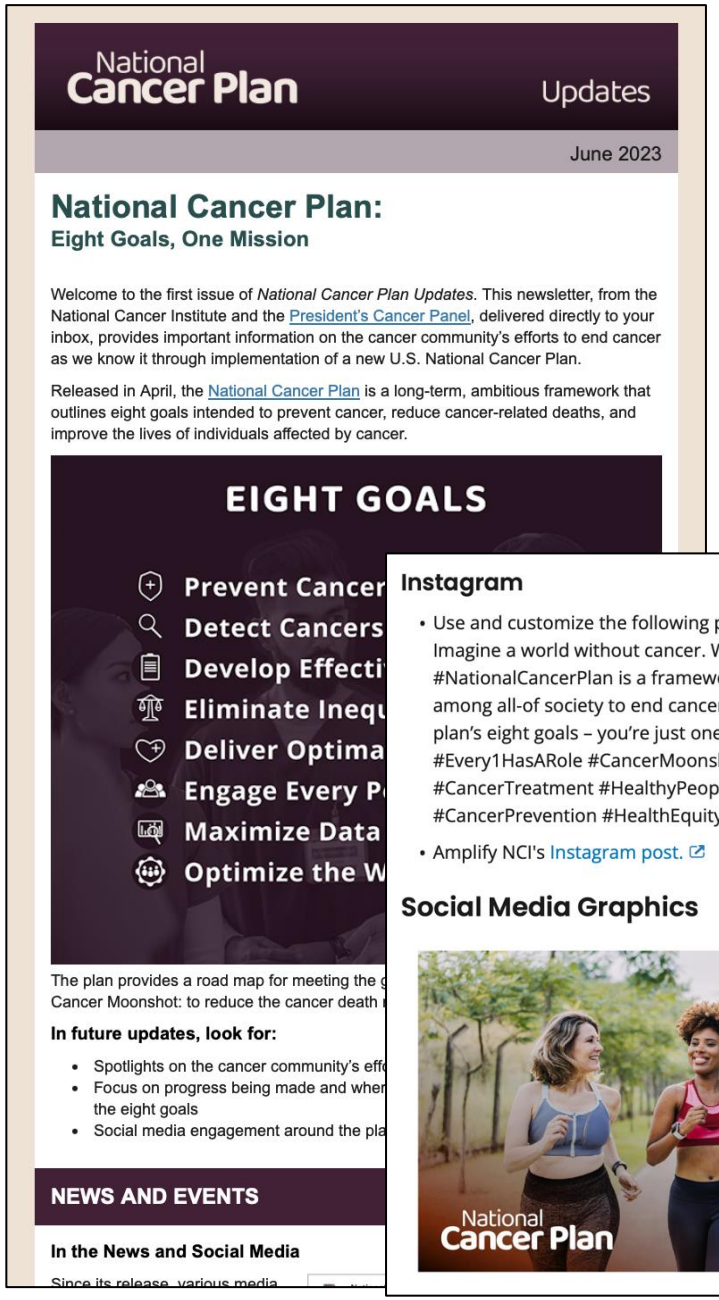
Prevent Cancer All people and society adopt proven strategies that reduce the risk of cancer	**Deliver Optimal Care** The health care system delivers to all people evidence-based, patient-centered care that prioritizes prevention, reduces cancer morbidity and mortality, and improves the lives of cancer survivors, including people living with cancer
Detect Cancers Early Cancers are detected and treated at early stages, enabling more effective treatment and reducing morbidity and mortality	**Engage Every Person** Every person with cancer or at risk for cancer has an opportunity to participate in research or otherwise contribute to the collective knowledge base, and barriers to their participation are eliminated.
Develop Effective Treatments Effective treatment, with minimal side effects, is accessible to all people with all cancers, including those with rare cancers, metastatic cancers, and treatment-resistant disease	**Maximize Data Utility** Secure sharing of privacy-protected health data is standard practice throughout research, and researchers share and use available data to achieve rapid progress against cancer
Eliminate Inequities Disparities in cancer risk factors, incidence, treatment side effects, and mortality are eliminated through equitable access to prevention, screening, treatment, and survivorship care	**Optimize The Workforce** The cancer care and research workforce is diverse, reflects the communities served, and meets the needs of all people with cancer and those at risk for cancer, ensuring they live longer and healthier lives

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 Effecti
Eliminate Inequ
Deliver Optima
Engage Every P
Maximize Data
Optimize the W

The plan provides a road map for meeting the g
Cancer Moonshot: to reduce the cancer death

In future updates, look for:

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

NEWS AND EVENTS

In the News and Social Media

Since its release, various media

Newsletter, June 2023

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

Digital Toolkit sample assets

Contributions to the National Cancer Plan

Spotlight: University of Colorado Cancer Center

- Collaborating with 9 counties in southeast Colorado to promote a smartphone app that helps people reduce tobacco use and vaping.
- Offers patient navigation for parents of adolescents and young adults about the HPV vaccine.
- Provides free colon cancer and radon screening kits at health fairs.

- Partnering with hospitals that serve low-income patients – regardless of insurance coverage – to offer free colorectal cancer screening and patient navigation services for people who need it.

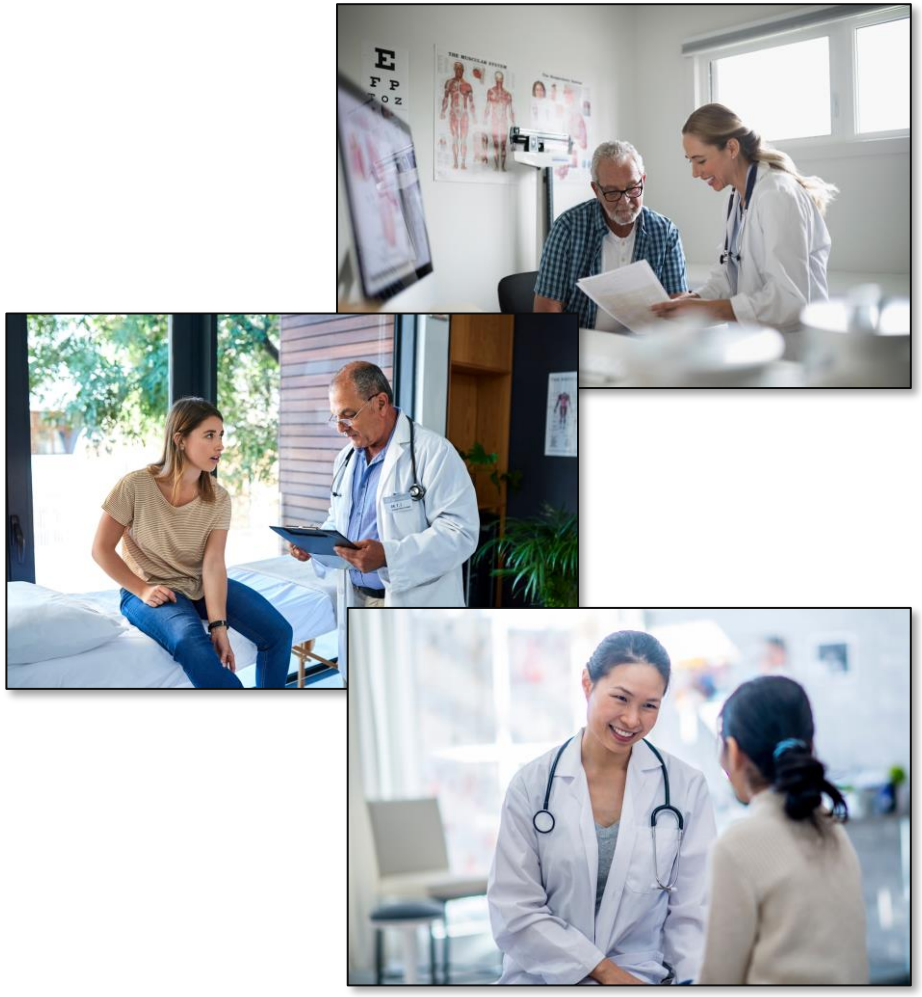
- Hosting events to educate researchers across the U.S. about new early detection methods, clinical trials that focus on improving immunotherapy for pancreatic cancer, and new technology to better visualize cell types that make up pancreatic tumors.

- A Rural Cancer Advisory Board advises the center's researchers from a rural patient/caregiver perspective.
- Launched a set of 5 studies addressing disparities in care and outcomes for Black and Hispanic communities related to head and neck cancers, lung cancer, and genetic cancer screening.

- Conducting outreach with Denver Health to reach diverse populations and identify eligible patients for clinical trials.
- Built a team of nurse navigators who work with clinical trial participants, including a Spanish-speaking navigator.

- Created a Community Advisory Council that engages with community members across the state to improve knowledge and awareness of cancer risk factors, screening services, and treatment options.

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 proposals received June 12

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

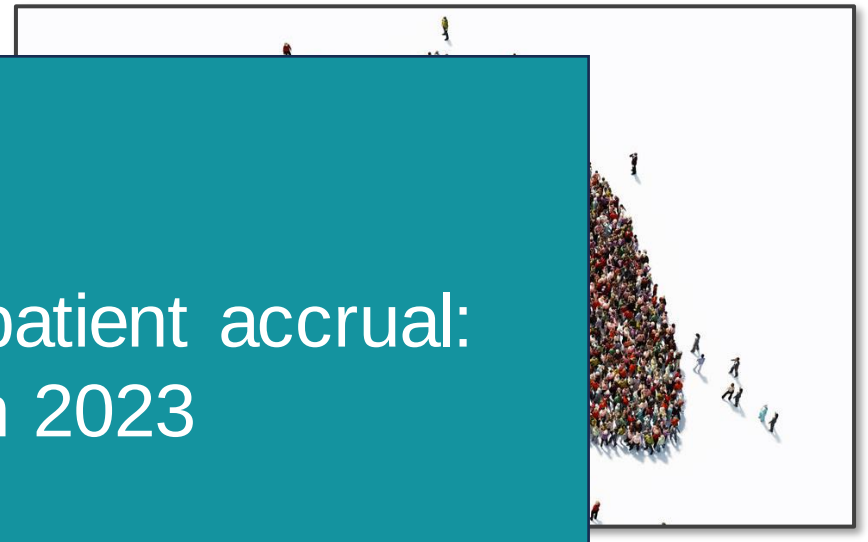
Pragmatica-Lung Study (S2302)

A streamlined model for future cancer clinical trials

Designed to:

- **Elimina**
- **Increas**
- **Stream** executi
- **Use foc collecti**
- Comple

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



uate whether ramucirumab + pembrolizumab combination therapy improves overall survival over standard treatment in people with advanced NSCLC.

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

Image: iStock

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

Trials open for enrollment	
Combination therapy trial	***Patients matched to trial***
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*

NCI Personnel Update

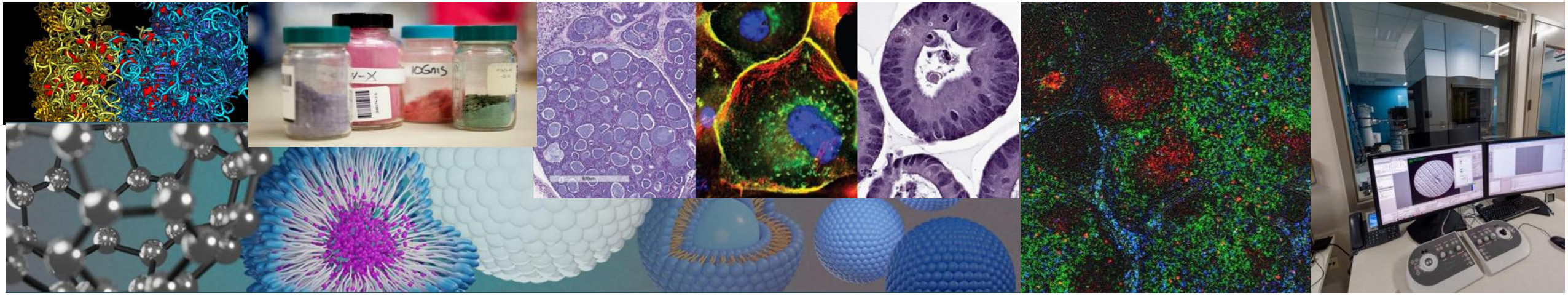
James L. Gulley, M.D., Ph.D.

NCI Clinical Director

Core FNL Resources and Programs Available to the Extramural Research Community

- National Cryo-Electron Microscopy Facility
- Nanotechnology Characterization Laboratory
- Laboratory Animal Sciences Program
- Mouse Models
- Cancer Imaging Archive
- Natural Products
- Preclinical Biologics Repository (Reagents)
- Preclinical Development
- Genomic Data Commons
- Cancer Research Data Commons
- Patient-Derived Models Repository
- Human SARS-CoV-2 Serology Standard
- Antibody Characterization Laboratory
- Imaging Mass Cytometry Laboratory
- Cell Therapy Manufacturing
- HIV/AIDS / SIV (Simian Immunodeficiency Virus) Research
- …and more

Learn more: ***frederick.cancer.gov/resources***



NCI-Designated Cancer Centers Updates

University of Florida Health Cancer Center
Gainesville, FL

- **Gained NCI designation in 2023**
- Director: Jonathan D. Licht, MD
- Serves north central Florida, a large region with the highest rates of cancer mortality in the state, high rates of poverty, rurality, and food, housing, and medical care insecurity
- Blends comprehensive patient care and innovative research in a collaborative, multidisciplinary environment

Massey Cancer Center at Virginia Commonwealth University
Richmond, VA

- **Gained "Comprehensive" status in 2023**
- Received NCI designation in 1975
- Director: Robert A. Winn, MD
- Serves central, southern, and eastern Virginia
- Uses a "community-to-bench" model to ensure consistent integration of community input into Massey's cancer research, education, care, and policy initiatives

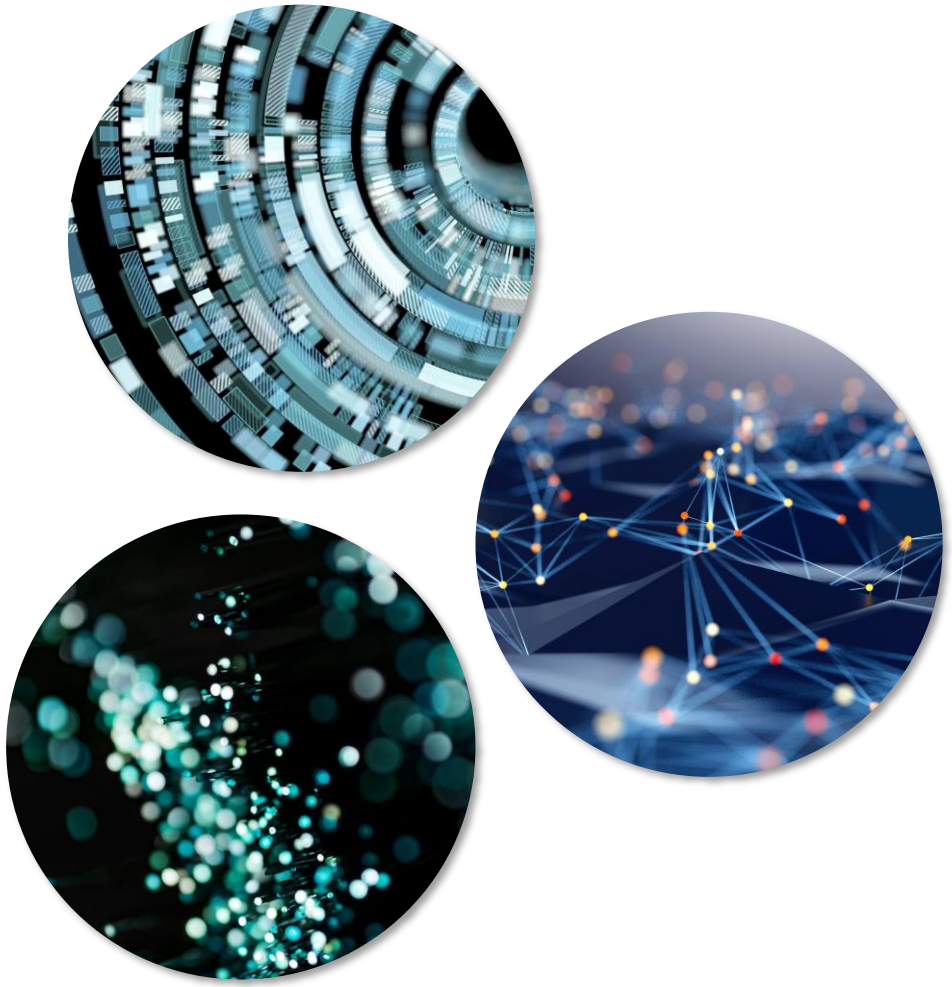
First NCI Deputy Director for Data Science

Seeking a highly qualified, visionary leader working in the field of data science, who will:

- Guide key data science initiatives (including implementing the NIH Strategic Plan for Data Science)
- Lead NCI in efforts to collect, store, analyze, and share basic, translational, and clinical research data
- Build strategic partnerships to develop and disseminate advanced technologies and methods
- …and more

For full details and to apply, visit: hr.nih.gov/jobs

Application deadline: August 25, 2023



Thank you!

www.cancer.gov

www.cancer.gov/espanol

1-800-4-CANCER

NCIinfo@nih.gov

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@TheNCI

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Recognition Ceremony

Thank You!

Outstanding and Dedicated Service to NCI and CTAC

Nancy E. Davidson, M.D.

Michael V. Knopp, M.D.

Neal J. Meropol, M.D.