NCI Director's Report

Norman E. Sharpless, M.D.

84th Meeting (virtual) of the NCI Council of Research Advocates

Wednesday, September 29, 2021

@NCIDirector @TheNCI





Division of Cancer Control and Population Sciences Leadership



Robert T. Croyle, Ph.D.

Director

NCI Division of Cancer Control and
Population Sciences

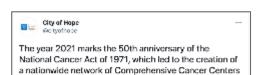
Retiring December 2021



Katrina Goddard, Ph.D.
Kaiser Permanente Center
for Health Research
Incoming DCCPS Director
pending final reviews

Commemoration across the Community

Cancer Centers



cityofhope.org/breakthroughs/.... @theNCI #NothingWillStopUs

the National Cancer Institute.



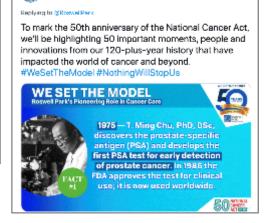
Memorial Sloan Kettering Cancer Center •

Did you know MSK opened the world's 1st #Pediatric Day Hospital to care for kids with cancer? This step allowed for our youngest patients to be seen on an outpatient basis, allowing them to return home on the day of treatment. #CancerResearchMonth #NothingWillStopUs #TBT #MSKKids









Roswell Park 👩

@RoswellPark

Cancer Organizations



Stand Up To Cancer 🕏



Govt. Organizations





cancer.gov > National Cancer Act 50th Anniversary Commemoration **PATIENTS AS PARTNERS** IN DISCOVERY AND PROGRESS Commemorating the signing of the National Cancer Act of 1971 0:00 / 1:47 YouTube []



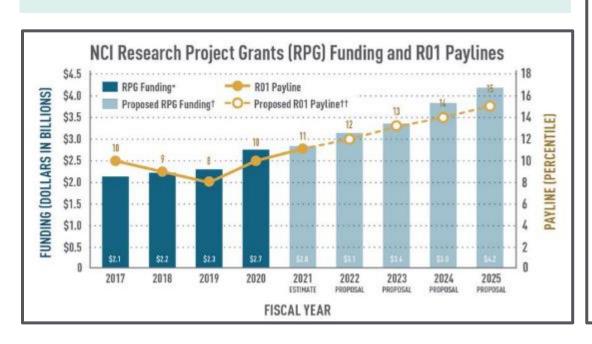


Annual Plan & Budget Proposal for Fiscal Year 2023



NCI PROFESSIONAL JUDGMENT BUDGET PROPOSAL FOR FISCAL YEAR 2023

(DOLLARS IN MILLIONS)



FISCAL YEAR 2021 NCI BASE APPROPRIATION	\$6,365 ⁻		
TOTAL BUDGET INCREASE (Proposed Allocation)	\$1,185 ⁺	\$165 \$185 \$150 \$205 \$125	Inflation Adjustment ^{††} Cancer Biology Research Cancer Prevention Research Cancer Detection & Diagnosis Research Cancer Treatment Research Public Health & Cancer Control Research Training & Infrastructure
FY 2023 BUDGET RECOMMENDATION	\$7,550		
FY 2023 CANCER MOONSHOT SM FUNDING	\$216		
FY 2023 TOTAL	\$7,766		





National costs for cancer care were estimated to be

\$190.2 billion in 2015 \$208.9 billion in 2020

Modeled annual productivity cost from cancer mortality

\$147.6 billion for 2020

Cathy J. Bradley, K. Robin Yabroff, Bassam Dahman, Eric J. Feuer, Angela Mariotto, Martin L. Brown, Productivity Costs of Cancer Mortality in the United States: 2000–2020, JNCI: Journal of the National Cancer Institute, Volume 100, Issue 24, 17 December 2008, Pages 1763–1770.



If you think research is expensive, try disease!

Mary Lasker



NCI Appropriations FY 2015 – 2021 (in millions)

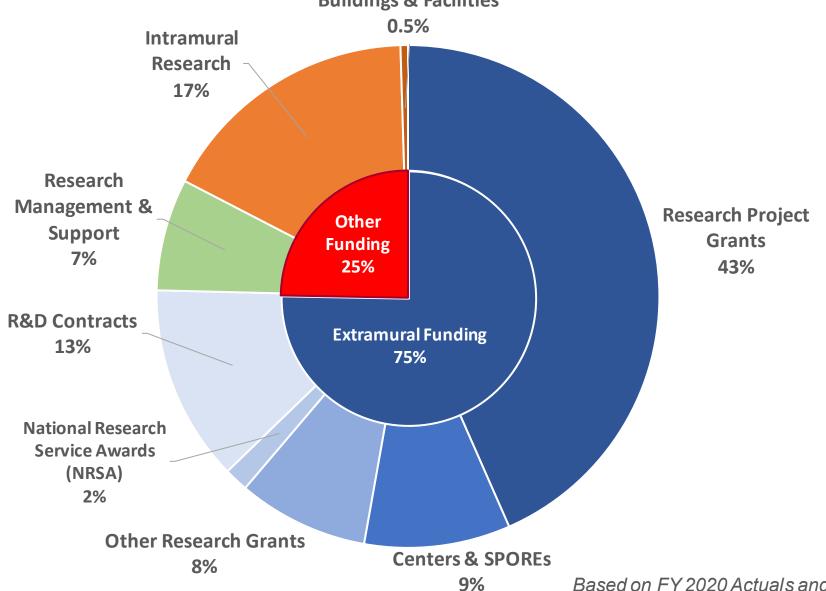
21st Century Cures Act - orange Childhood Cancer Initiative - green





How does NCI spend its money?

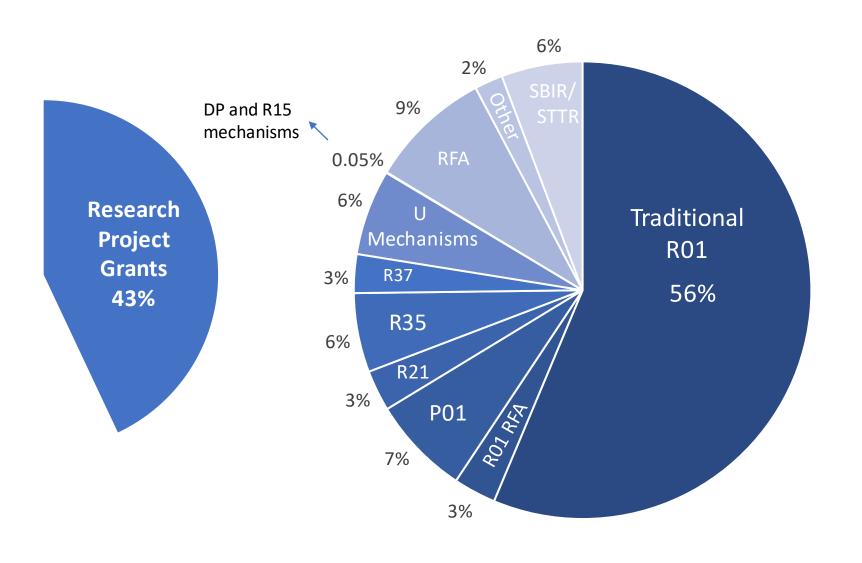
Buildings & Facilities







FY 2020 Research Project Grants



- R01 Traditional
- R01 RFA
- P01 Program Projects (Excludes RFA)
- R21 (Excludes RFA)
- **R**35
- R37
- U01, U19, U43, UM1, UH2, UH3, UG3 (Excludes RFA)
- DP1, DP2, DP5, R15 (Excludes RFA)
- RFA (Excludes R01 RFA)
- Other (R33, R00, R03, R50, R56)
- SBIR/STTR



Childhood Cancers



Childhood Cancer Data Initiative Overview & Progress Webinar September 13, 2021



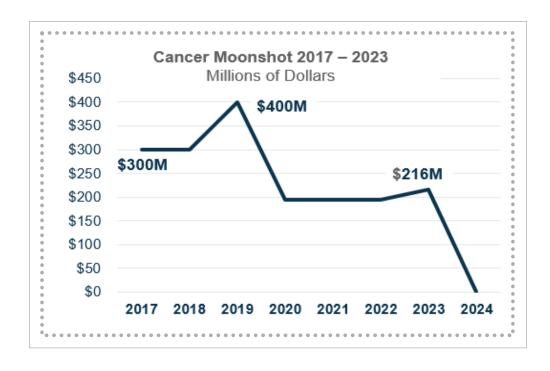


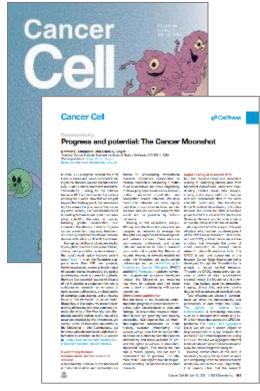
Cancer Currents: An NCI Cancer Research Blog Seeing a Promising Future for Progress against Childhood Cancer

September 16, 2021, by Norman E. Sharpless, M.D.

NCI Director Dr. Ned Sharpless discusses progress against childhood cancers, like CAR T-cell therapy and collecting more comprehensive data on children and adolescents with cancer, and the need to better address disparities in childhood cancer.

Cancer MoonshotSM





Cancer Cell July 12, 2021 **Progress and Potential: The Cancer Moonshot**

Norman E. Sharpless Dinah S. Singer

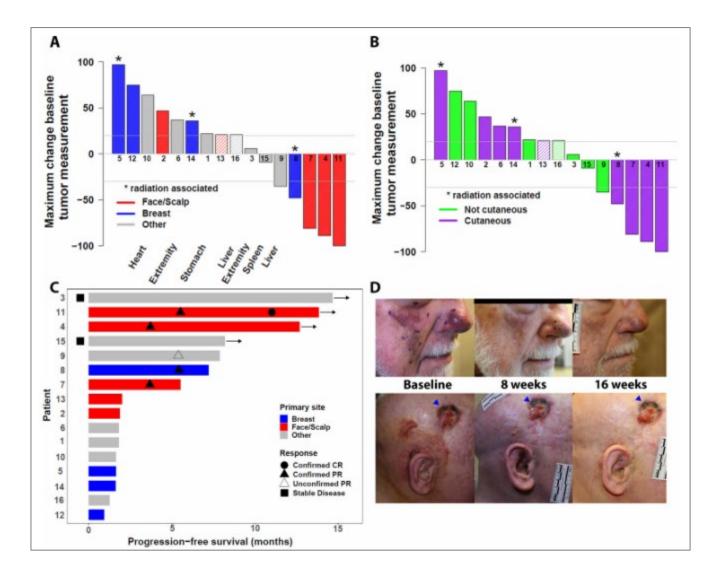


Blue Ribbon Panel Report Anniversary Seminar: Reflections, Progress, and Potential of the Cancer Moonshot September 9, 2021

DART: Dual Anti-CTLA-4 & Anti-PD-1 blockade in Rare Tumors

Prospective, open-label, multicenter phase II clinical trial of ipilimumab plus nivolumab for angiosarcoma

- Sub-study N=16
- Tumors in 4 patients partially or completely responded to treatment
- Two patients maintained stable disease on the drug combination >6 months
- Some responses sustained for over one year
- One patient had tumors disappear entirely





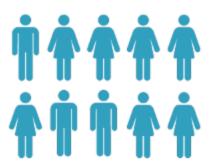


SHERLOCK LUNG

Tracking Lung Cancer Mutational Processes in Never Smokers

232 Patients

General Population Never Smokers European Descent



Whole Genome Sequencing

Tumor Tissue 85x Blood/Normal Tissue 32x

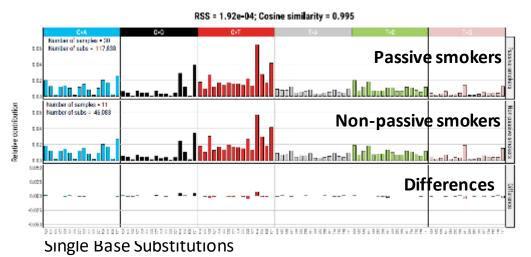


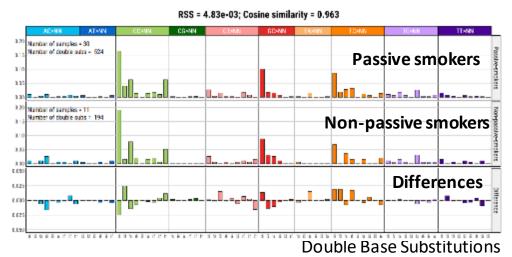
How Tumors Were Evaluated

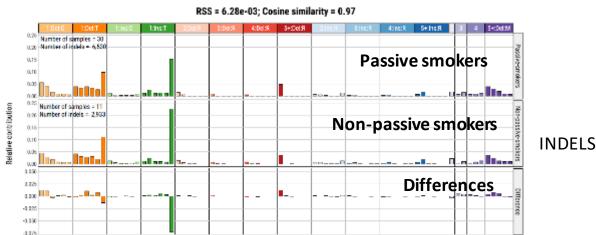
- Q Genomic Landscape
- Q Mutational Signatures
- Q Evolutionary History
- Molecular Subtypes
- Clinical Outcome



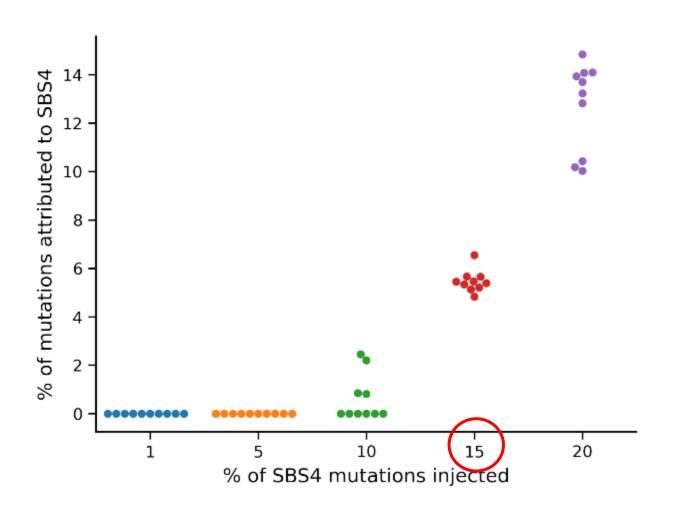
No SBS4 signature in tumors from subjects exposed to second-hand tobacco smoking







Detection limit of signature algorithm

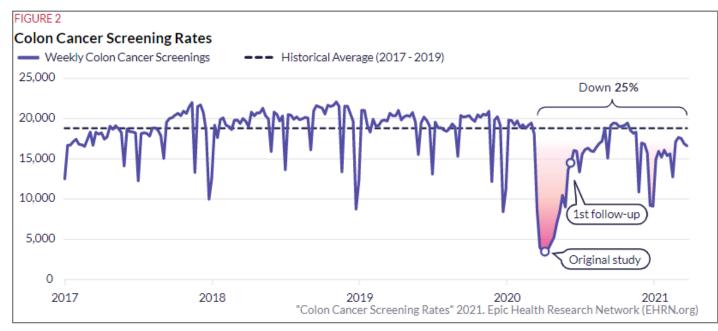


In accord with observational data: Second-hand smoke, RR=~10-20%

Active smoking, RR=~15-25-fold in comparison with never smokers



Cancer screening rates during the COVID-19 pandemic

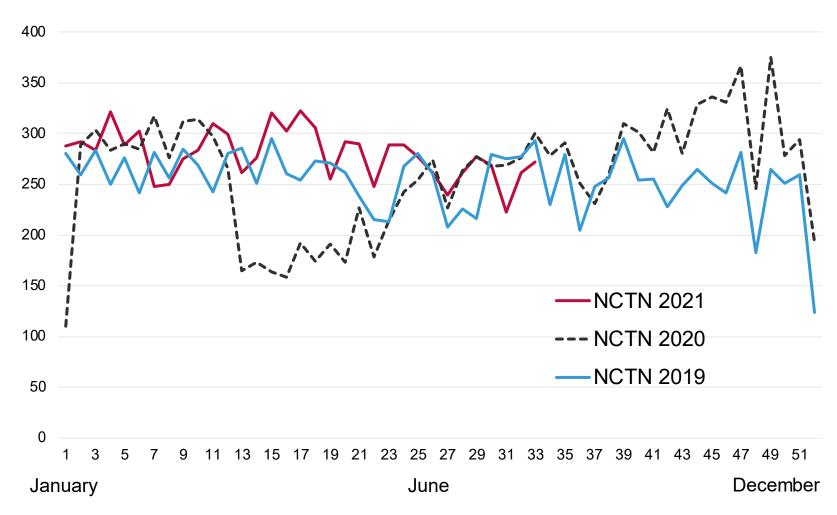


COSMOS STUDY: **Cancer Screenings Are Still Lagging** - 9 Jun 2021 Abstract: While cancer screenings briefly returned to baseline, we have not fully recovered from the initial drop reported in May 2020. *Christopher Mast, MD | Alejandro Muñoz del Río, PhD | Tyler Heist, PhD*

"These missed screenings continue to raise concern of an increase in later stage cancer diagnoses with potential poorer prognosis. While our findings suggest the gap is decreasing, continued diligence is needed to make up for the missed screenings."



NCTN trial enrollment during the COVID-19 pandemic, by week





Highlights of NCI's SARS-CoV-2 Serology Activities

Antibody test performance evaluation with FDA

 ~ 350 tests received; 130 evaluations completed

Shuren J, Stenzel T. The FDA's Experience with Covid-19 Antibody Tests. N Engl J Med. 2021 Feb 18;384(7):592-594.

Work with All of Us showing timeline of early seroconversion in US

Althoff KN, et al, Antibodies to SARS-CoV-2 in All of Us Research Program Participants, January 2-March 18, 2020, Clinical Infectious Diseases, 2021.

COVID-19 Seroprevalence Studies Hub (SeroHub)

https://covid19serohub.nih.gov/

Standard reference serum

 Standard shipped to >31 requestors; now shipping to more requestors referred by WHO (depleted supply)

First demonstration that antibody status correlates with reduced risk of infection

Harvey, et al. JAMA Internal Medicine. Feb 24, 2021.

NCI COVID-19 in Cancer Patients Study (NCCAPS)

- >1200 adult and >75 pediatric COVID-19 patients enrolled
- >800 trial sites (all 50 States, DC, PR, Canada)

NCI Serological Sciences Network for COVID-19 (SeroNet)



- 8 U54 Centers of Excellence
- 13 U01 Research Projects
- 4 Capacity Building Centers (contracts)
- FNL Serology Lab & Network Coordinating Center
- >90 publications; >30 preprints

Repeated Cross-Sectional Sero-Monitoring of SARS-CoV-2 in New York City

Stadlbauer, et al. Nature, 590(7844):146-150, February 2021

Impact of SARS-CoV-2 variants on the total CD4+ and CD8+ T cell reactivity in infected or vaccinated individuals

Tarke, et al. Cell Reports Medicine, Volume 2, Issue 7, July 20, 2021

Infection and Vaccine-Induced Neutralizing-Antibody Responses to the SARS-CoV-2 B.1.617 Variants

Edara, et al. NEJM, August 12, 2021

Humoral signatures of protective and pathological SARS-CoV-2 infection in children

Bartsch, et al. Nature Medicine, 27(3):454-462, March 2021

Durable Humoral and Cellular Immune Responses 8 Months after Ad26.COV2.S Vaccination

Barouch, et al. New England Journal of Medicine 385, 951–953, September 2, 2021

CUSP2CT Connecting Underrepresented Populations to Clinical Trials

PURPOSE

To implement and evaluate multi-level and culturally tailored outreach and education interventions with the primary goal to increase referral of racial/ethnic minority populations to NCI-supported clinical trials.

CUSP2CT Network FY 22-26

- Data, Evaluation, and Coordinating Center 1 U24: RFA-CA-21-057
- Resource-Related Research Projects Up to 4 U01s: RFA-CA-21-058

Due November 19, 2021

NIH Faculty Institutional Recruitment for Sustainable Transformation (FIRST)

Morehouse School of Medicine	FIRST Coordination and Evaluation Center to promote inclusive excellence (U24) Cornell FIRST	
Cornell University		
Icahn School of Medicine at Mount Sinai	NIH FIRST Cohort Cluster Hiring Initiative at Icahn School of Medicine at Mount Sinai	
Drexel University	Catalyzing Systemic Change at Drexel University to Support Diverse Faculty in Health Disparities Research	
University of Alabama at Birmingham	UAB/Tuskegee Faculty Institutional Recruitment for Sustainable Transformation (UAB/TU FIRST) Partnership	
Florida State University	Fostering Institutional Resources for Science Transformation: The FLORIDA-FIRST Health-Science Brigade	
San Diego State University	SDSU FUERTE: Faculty United towards Excellence in Research and Transformational Engagement	



Cancer Diagnostic Devices (CD2) Interagency Task Force



The CD2 Task Force will

- Coordinate scientific and programmatic collaborations
- Discuss areas of regulatory and technical challenges to translation and implementation of cancer screening and diagnostic devices for near patient use
- Efforts will emphasize challenges of rural and medically underserved communities

Cancer as a Global Health Priority



VIEWPOINT

Satish Gopal, MD

National Cancer Institute, Rockville, Maryland.

Norman E. Sharpless, MD

National Cancer Institute, Rockville, Maryland. Percentage of NCI extramural awards that included international components

2010 9%

2020 13%

IN 2020

Among 1079 extramural awards involving non-US countries

342 (32%)

involved LMICs

Strategic priorities for the Center for Global Health include

- increasing the portfolio of NCI extramural funding involving LMIC collaborators
- targeting areas for extramural funding based on key scientific gaps in global cancer control
- promoting equity in global cancer research by supporting the independent scientific capacity of LMIC investigators and institutions

U.S.-U.K. Bilateral Cancer Summit



Doug Mills/The New York Times

"We will bring together researchers, patients, and other stakeholders to share ideas and identify opportunities for collaboration to accelerate advances in lifesaving approaches to cancer, which remains a leading cause of death worldwide."

Joint statement, June 10, 2021



- Planning event scheduled for November 2021
- Bilateral Summit Spring 2022

Updates to NCI Training Programs

- Increased flexibility for surgeonscientists under the K08 career development program
- Changes to stimulate greater inclusion and innovation within the T32 grant program for institutional research training
- Details of a new Early-Stage
 Surgeon-Scientist Program, to
 encourage surgeon-scientists to
 pursue careers in cancer science.



Special thanks to departing NCRA members!



Rick Bangs, MBA, PMP
Chair, Patient Advocate Committee
SWOG



Danielle Leach, MPA
Chief of Community and
Government Relations
National Brain Tumor Society

...and welcome to new NCRA members!



Vickie Buenger, Ph.D.
President Emeritus
Coalition Against Childhood Cancer



Melissa Buffalo, MS
Chief Executive Officer
American Indian Cancer Foundation

Discussion