

NCI Director's Report

*Clinical Trials and Translational Research
Advisory Committee (CTAC)*

Norman E. Sharpless, M.D.
November 10, 2021

@NCIDirector
@TheNCI

Commemoration across the Community

Cancer Centers

City of Hope
@cityofhope

The year 2021 marks the 50th anniversary of the National Cancer Act of 1971, which led to the creation of a nationwide network of Comprehensive Cancer Centers — the National Cancer Institute.
[cityofhope.org/breakthroughs/...](https://cityofhope.org/breakthroughs/) @TheNCI #NothingWillStopUs



Memorial Sloan Kettering Cancer Center
@mskcc

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 #TBI #MSKKids



Winship Cancer Institute of Emory University
@WinshipEmory

ICYMI: As part of the National Cancer Act's 50th Anniversary, @TheNCI is honoring Winship research leader Dr. Deborah Watkins Bruner as a changemaker for her work in patient-reported outcomes and symptom management. #NothingWillStopUs fal.on/3fDXt



Roswell Park
@RoswellPark

Replying to @RoswellPark

To mark the 50th anniversary of the National Cancer Act, we'll be highlighting 50 important moments, people and innovations from our 120-plus-year history that have impacted the world of cancer and beyond. #WeSetTheModel #NothingWillStopUs



Cancer Organizations

Lasker Foundation
@LaskerFdn

2021 is the 50th Anniversary of the National Cancer Act, which created a nationally coordinated #cancer research program led by @theNCI. Mary #Lasker played a critical role in passing this legislation. #NothingWillStopUs #SupportMedicalResearch ow.ly/9YFy50EDEQc



Stand Up To Cancer
@SU2C

50 years ago, the National Cancer Act of 1971 gave new hope to cancer research. Learn how the Act helped to change the course of cancer research and why we are commemorating its 50th anniversary throughout 2021. #NothingWillStopUs #StandUpToCancer



Govt. Organizations


Minority Health
@MinorityHealth

Progress has been made but there's still more to do to address cancer #HealthDisparities. Learn more over the next several weeks as we share stories and resources focused on NCI's commitment to reduce the burden of cancer for all. go.usa.gov/x6K6p #NothingWillStopUs



President's Cancer Panel
@PresCancerPanel

Reflections on the 50th Anniversary of the National Cancer Act. Read about the history of the panel and plans for the future prescancerpanel.cancer.gov/node/136 #NCA50 #NothingWillStopUs



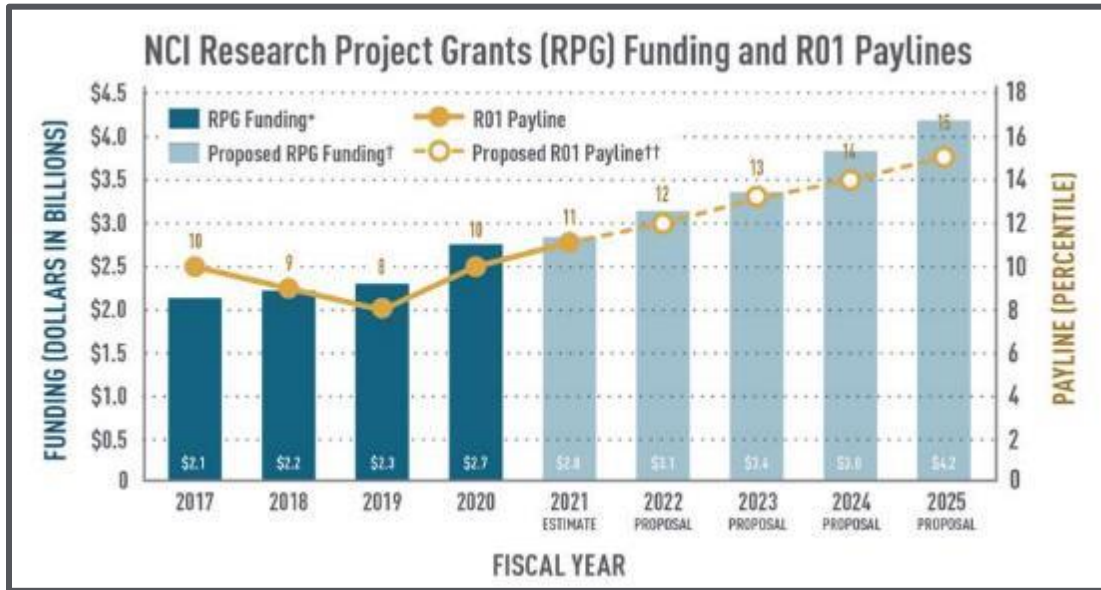
"We are not in search of a magic bullet, but rather are attempting to mobilize the best brains available in this nation and the world to ensure that they have an opportunity to make their maximum contribution to the cause of solving the cancer problem and of minimizing the time required for the solutions to benefit the cancer patient."

Dr. Benno C. Schmidt Sr.
First chair of the President's Cancer Panel



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†	<ul style="list-style-type: none"> \$277 Inflation Adjustment†† \$165 Cancer Biology Research \$185 Cancer Prevention Research \$150 Cancer Detection & Diagnosis Research \$205 Cancer Treatment Research \$125 Public Health & Cancer Control Research \$78 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.

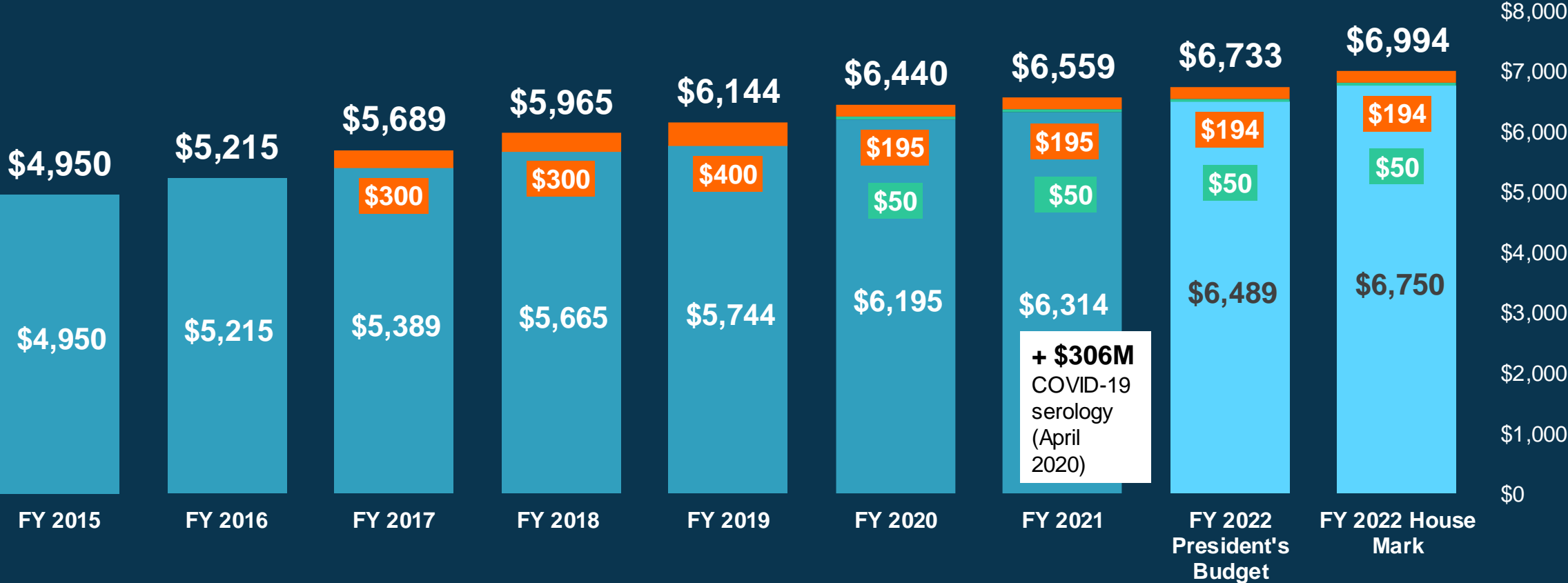


*If you think research is
expensive, try disease!*

Mary Lasker

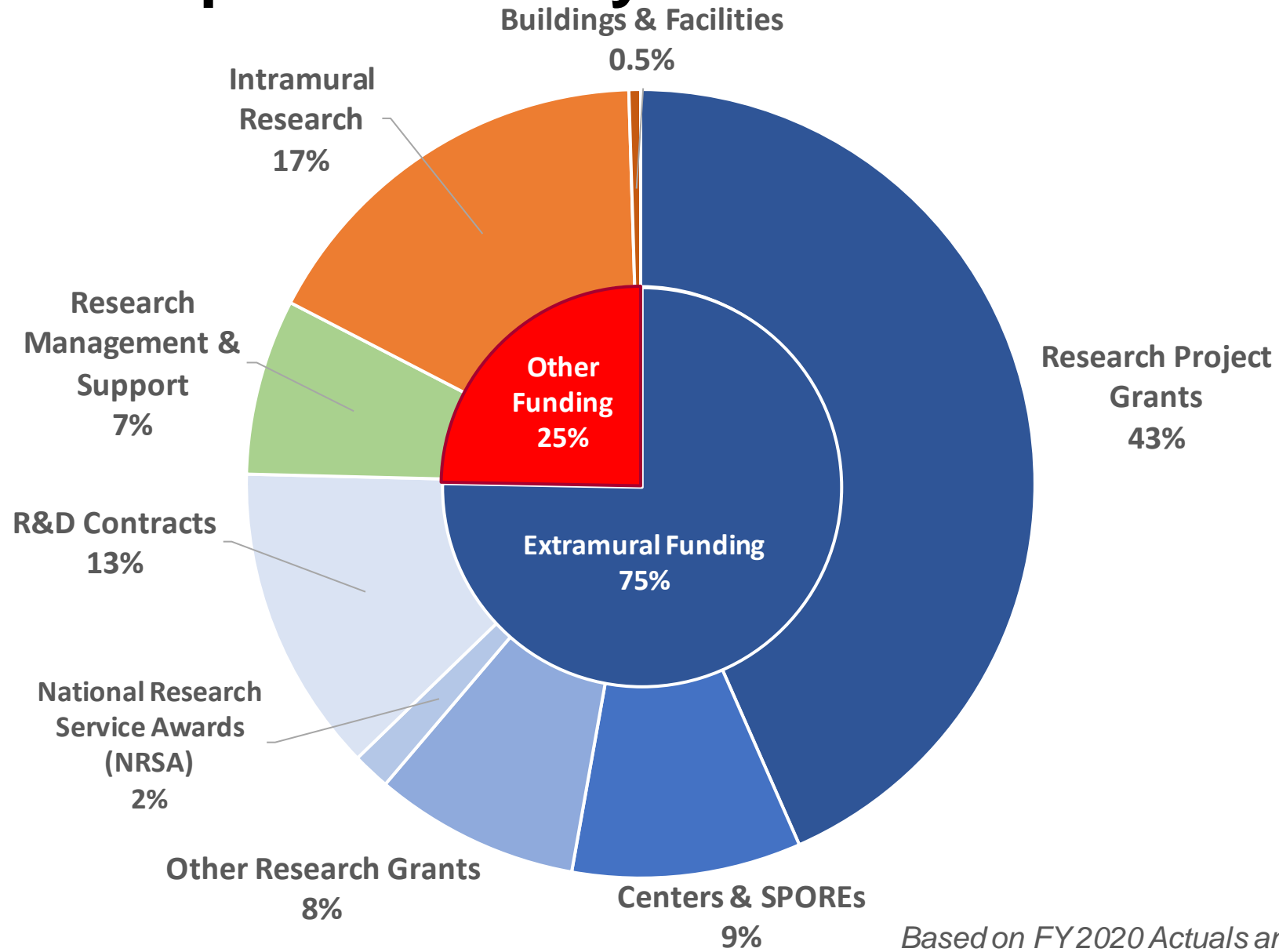
NCI Appropriations FY 2015 – 2022 (in millions)

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

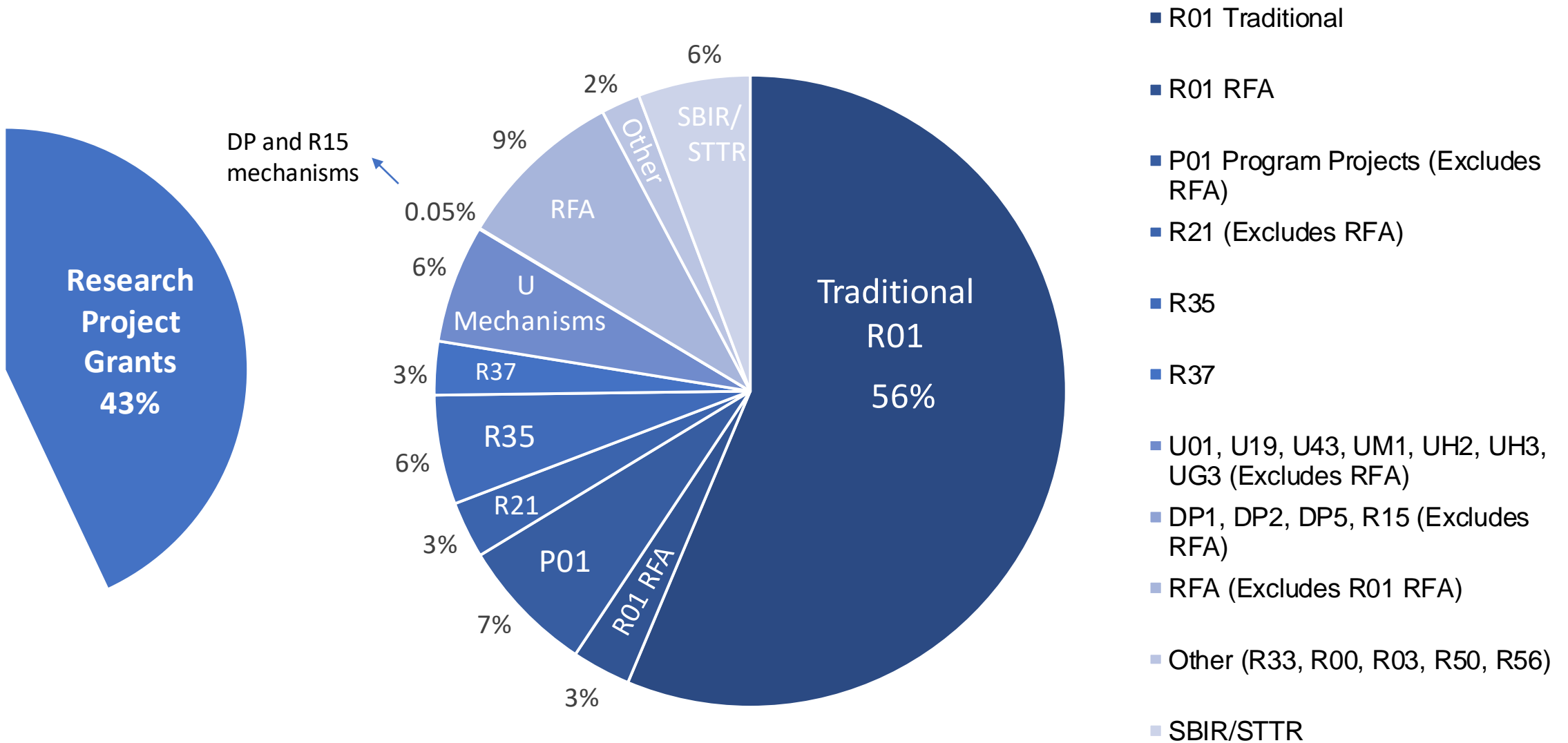


FY 22 Continuing Resolution expires December 3.

How does NCI spend its money?



FY 2020 Research Project Grants





NCTN Trials Added 14 Million Years of Life

September 20, 2021

Abstract 15030

- **163 trials**
- N=108,102 patients
 - 30.9% (163/528) of estimated trials conducted
- Most common: Breast (33), gynecologic (28), lung (15), prostate (12)
- Trials cited **166,771 times**
- **128** trials showed overall survival favoring the experimental arm

*These trials were estimated to have generated **gains of 14.0 million life-years** to cancer patients.*

NCI Strategic Vision for Clinical Trials: 2030 and Beyond

Develop **flexible, faster, simpler, less expensive, high-impact** clinical trials that seamlessly integrate with clinical practice

Streamline processes
for trial design and
execution

Focus on essential
endpoints

Decrease regulatory
hurdles and broaden
trial access

Increase efficiency of
data collection

NCI Clinical Trials and Translational Research Advisory Committee Strategic Planning Working Group Overview



Re-assess strategic vision for clinical trials system for 2030 and beyond



Review and address necessary clinical trials infrastructure



Developed recommendations and initiatives

15
3 operational

Themes:

Trial Complexity and Cost

Decentralized Trial Activities

Promoting Accrual and Access

New Data Collection Approaches

PRO Data for Clinical Trials

Operational Burden

Statistical Issues

Workforce Outreach and Training

Childhood Cancers



Childhood Cancer Data Initiative Annual Symposium November 9, 2021

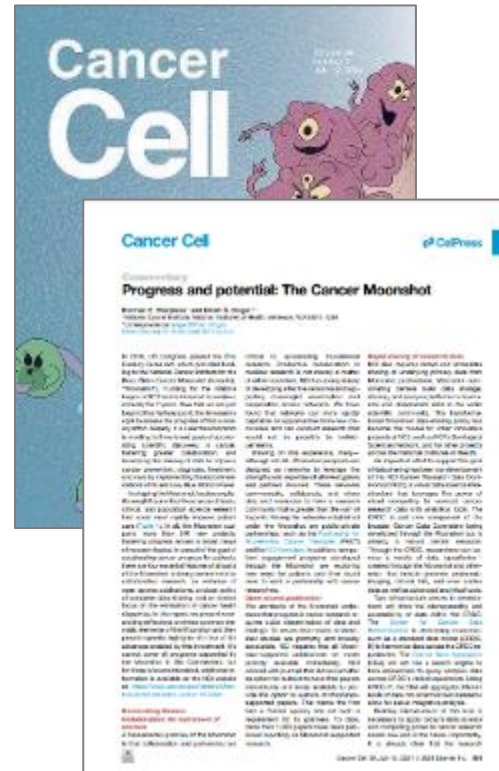
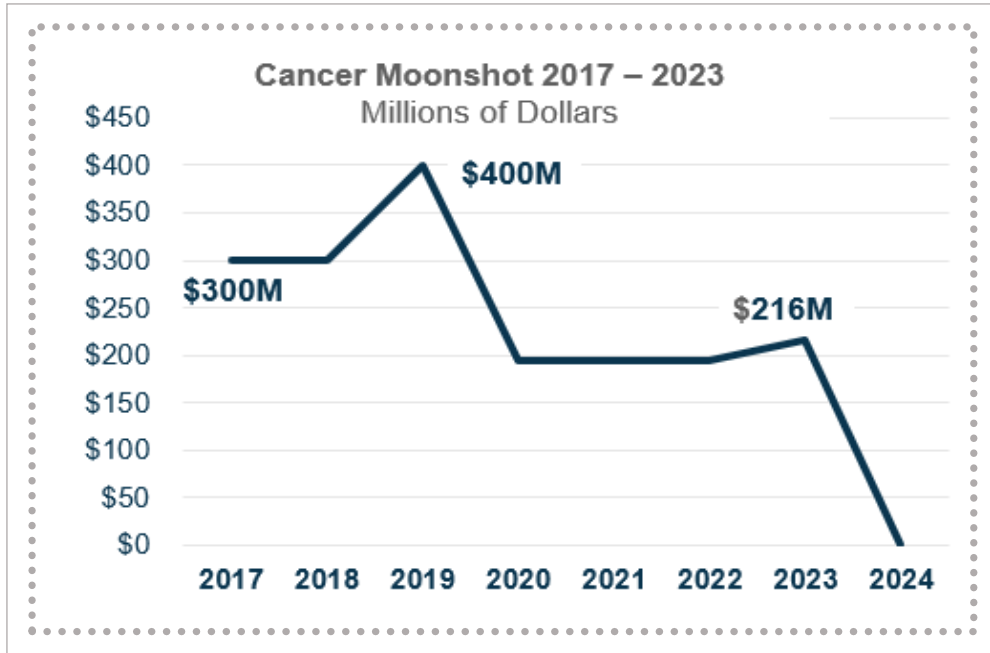


Cancer Currents: An NCI Cancer Research Blog **Seeing a Promising Future for Progress against Childhood Cancer**

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



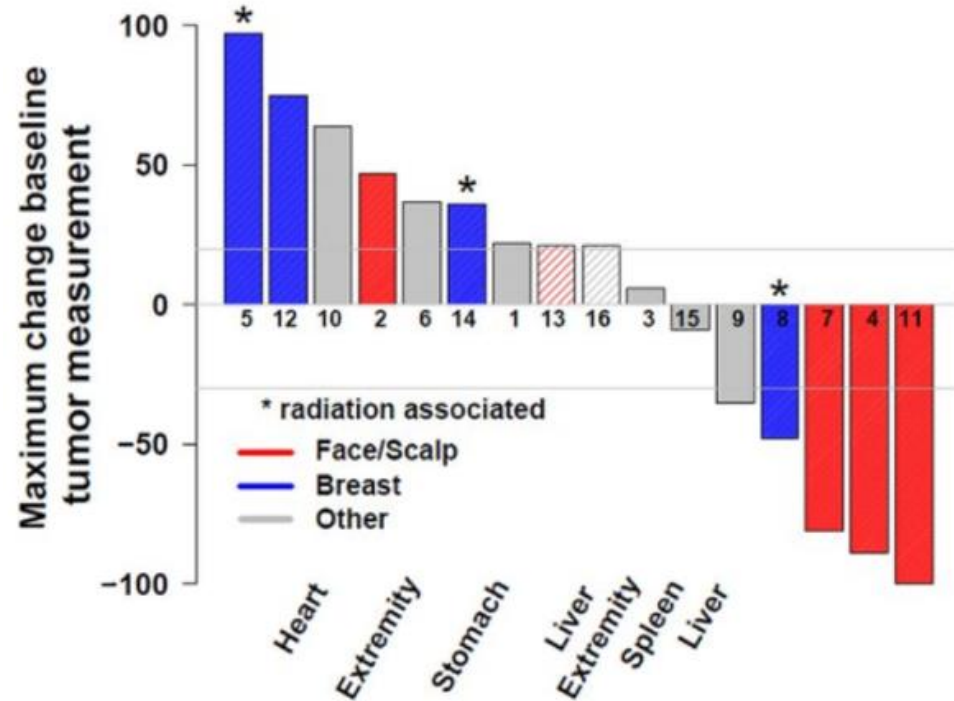
Cancer Cell July 12, 2021
Progress and Potential: The Cancer Moonshot
 Norman E. Sharpless
 Dinah S. Singer



Cancer Moonshot Seminar Series
(Virtual). Available on Youtube.

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

Recent results in angiosarcoma



Baseline

8 weeks

16 weeks

DART | SWOG 1609

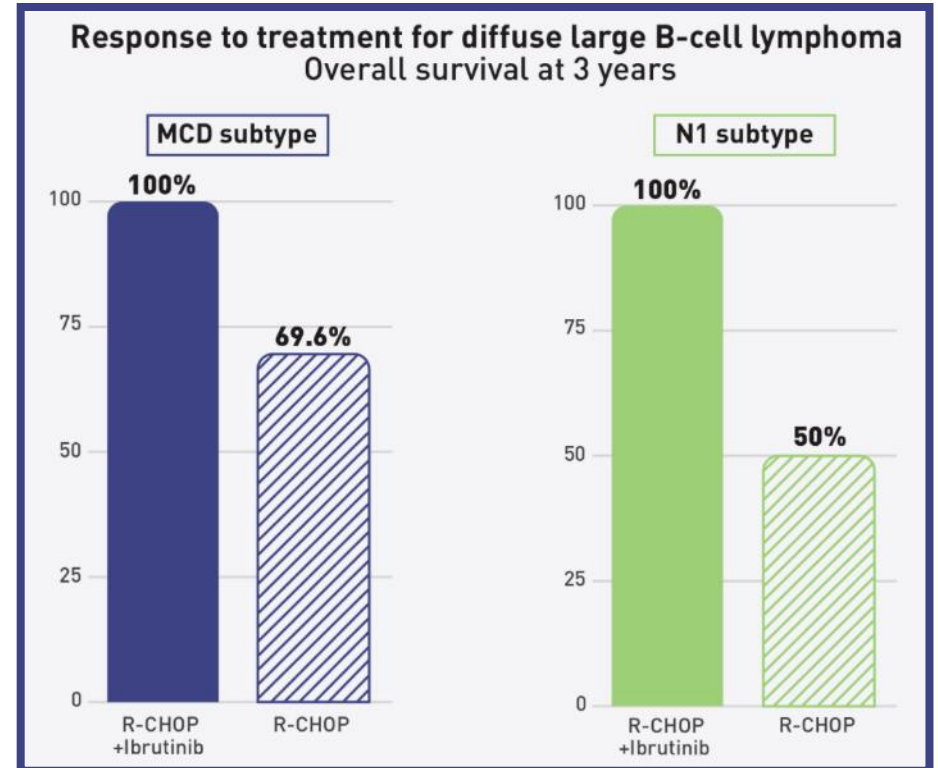
- Launched in 2017
- 53 cohorts based on condition
- Recruitment for some cohorts ongoing

Ibrutinib improves survival for younger people with diffuse large B-cell lymphoma

NCI Press Release: November 4, 2021

“People thought the trial didn’t work, but...if you just considered younger patients under the age of 60, they had a real benefit from ibrutinib.”

Louis M. Staudt, M.D., Ph.D., Chief
Lymphoid Malignancies Branch, NCI



Wilson WH, et al. Effect of ibrutinib with R-CHOP chemotherapy in genetic subtypes of DLBCL. *Cancer Cell*. 2021 Nov 3;S1535-6108(21)00557-2. doi: 10.1016/j.ccell.2021.10.006. Epub ahead of print. PMID: 34739844.

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 University	Cornell FIRST
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

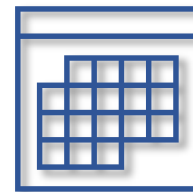
U.S.-U.K. Bilateral Cancer Summit



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



- Scientific Summit – November 2021
- Leadership Summit – Spring 2022

Updates to NCI Training Programs

- Increased **flexibility for surgeon-scientists 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.



NCI Bottom Line: A Blog about Grants and More



NCI Updates Training Programs to Support Cancer Researchers of the Future

August 3, 2021, by Dr. Oliver Bogler

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*

Discussion