

# NCI Director's Report

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Norman E. Sharpless, M.D.

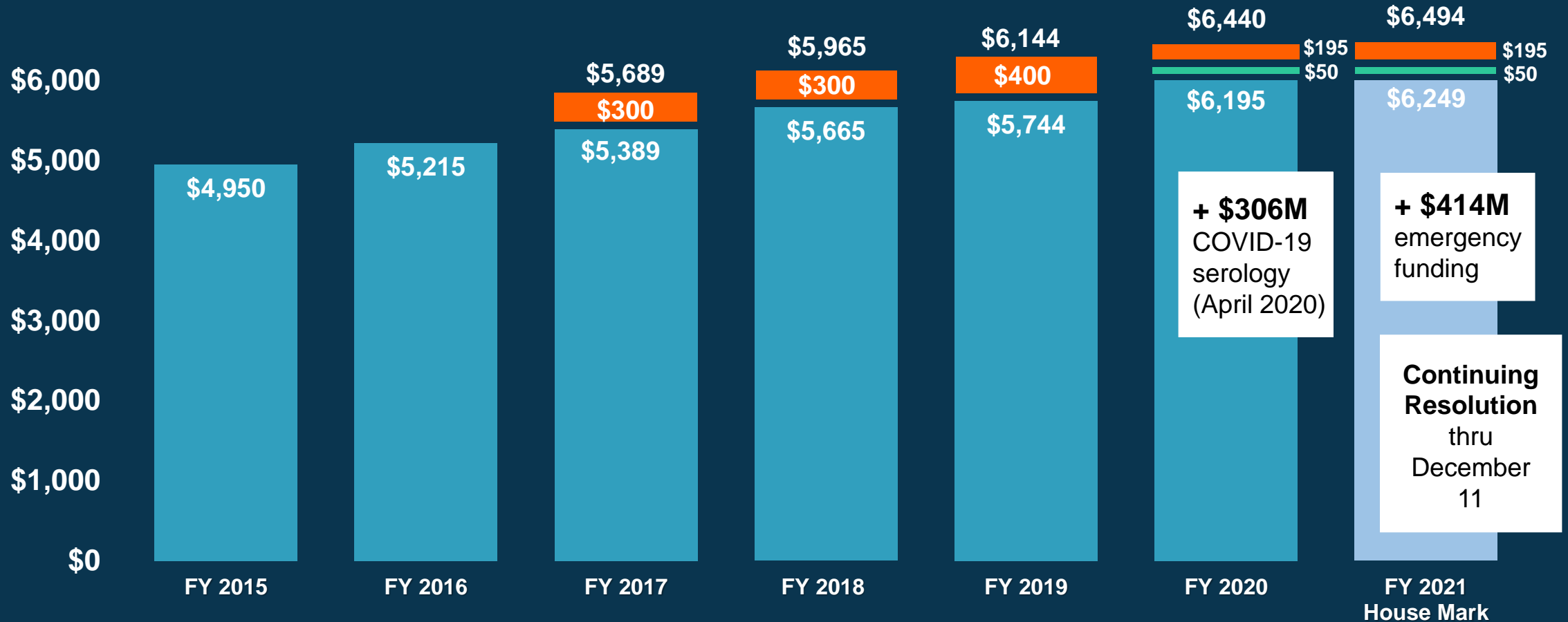
*Clinical Trials and Translational Research Advisory  
Committee*

*November 4, 2020*

@NCIDirector  
@TheNCI

# NCI Appropriations FY 2015 – 2020 (in millions)

21<sup>st</sup> Century Cures Act - orange  
Childhood Cancer Initiative - green





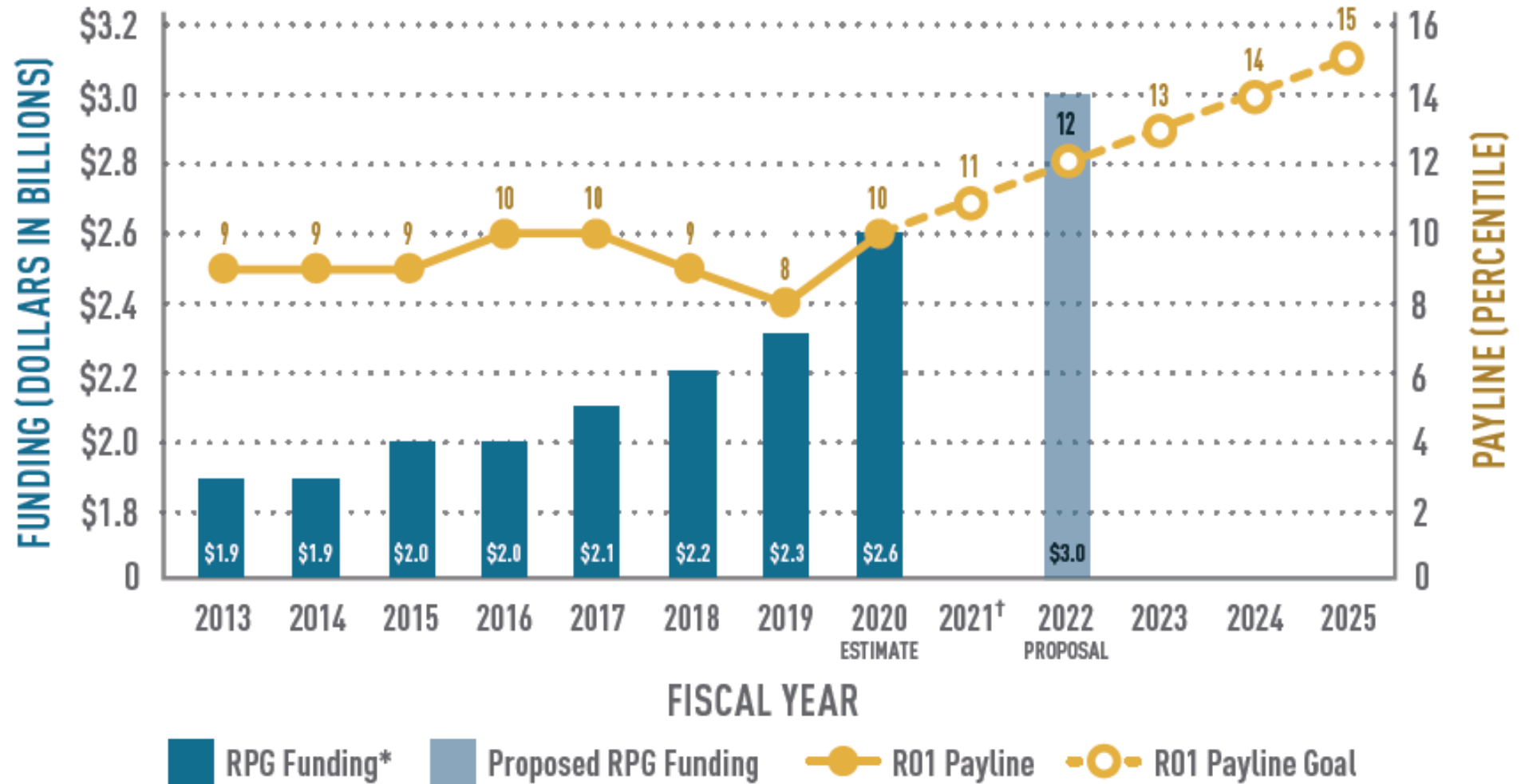
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# ANNUAL PLAN & BUDGET PROPOSAL

Fiscal Year 2022

[cancer.gov/research/annual-plan](https://cancer.gov/research/annual-plan)

# NCI Research Project Grants (RPG) Funding and R01 Paylines



\* RPG funding levels exclude small business grant set-asides.

<sup>†</sup> FY 2021 appropriations not yet finalized.

OXFORD  
ACADEMIC



JOURNAL of the  
NATIONAL CANCER INSTITUTE

ACCEPTED MANUSCRIPT

# COVID-19, Social Justice, and Clinical Cancer Research FREE

James H Doroshov, M.D. ✉, Sheila Prindiville, M.D, Wortia McCaskill-Stevens, M.D,  
Margaret Mooney, M.D, Patrick J Loehrer, M.D

*JNCI: Journal of the National Cancer Institute*, djaa162,  
<https://doi.org/10.1093/jnci/djaa162>

**Published:** 15 October 2020    **Article history** ▼

# NCI Response to COVID-19

- SARS-CoV-2 serology research
- NCI COVID-19 in Cancer Patients Study (NCCAPS)
- Guidance and special procedures for cancer clinical trials
- Flexibilities and opportunities for grantees
- Genomic studies of COVID-19 outcomes

***[cancer.gov/coronavirus-researchers](https://cancer.gov/coronavirus-researchers)***

# Adapting Clinical Trials during the Pandemic

- Patient care can be transferred to different participating study sites
- Local healthcare providers can provide study activities to provide continuity of care (oversight by responsible investigator)
- NCI and trial sites can ship oral drugs directly to patients
- Alternative procedures that do not compromise safety or the integrity of the study will be considered minor deviations
- NCI CIRB supports “remote” informed consent: telephone discussion in conjunction with patient signature on written document



# Supplemental funding from Congress

- Enacted April 24th
- \$306M for NCI to **develop, validate, improve, and implement** serological testing and associated technologies
- COVID-19-focused and distinct from annual appropriation

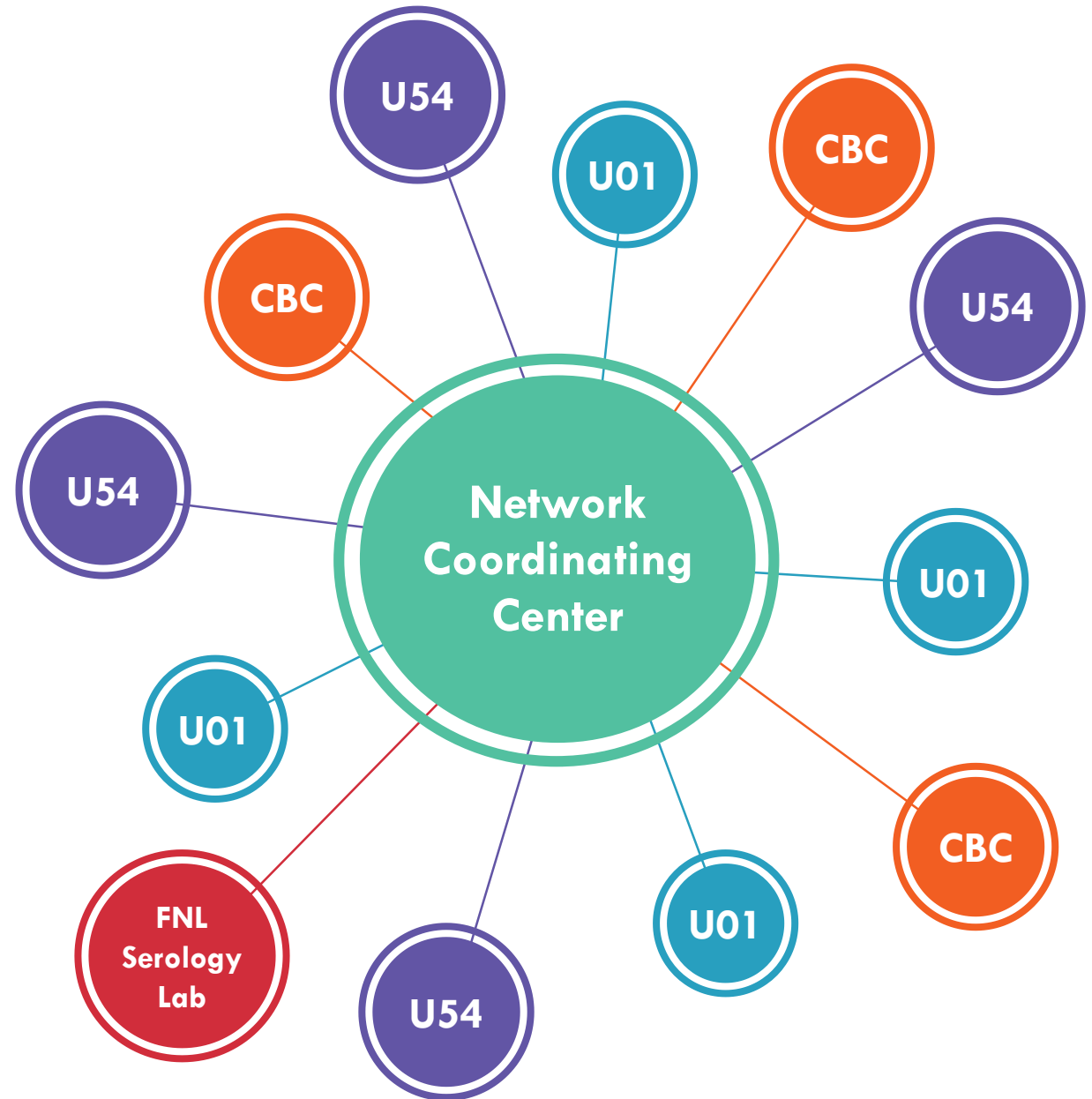
134 STAT. 620	PUBLIC LAW 116-139—APR. 24, 2020
	Public Law 116-139 116th Congress
	An Act
<u>Apr. 24, 2020</u> [H.R. 266]	Making appropriations for the Department of the Interior, environment, and related agencies for the fiscal year ending September 30, 2019, and for other purposes.
	<i>Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,</i>
Paycheck Protection Program and Health Care Enhancement Act. 15 USC 9001 note.	<b>SECTION 1. SHORT TITLE.</b> This Act may be cited as the “Paycheck Protection Program and Health Care Enhancement Act”.
	<b>SEC. 2. TABLE OF CONTENTS.</b> The table of contents for this Act is as follows:
	Sec. 1. Short title. Sec. 2. Table of contents. Sec. 3. References.



# SeroNet Serological Sciences Network

- Grants (U54s and U01s)
- Contracts (CBCs)
- National Laboratory

***Launched October 8***



# NCI COVID-19 in Cancer Patients Study (NCCAPS)



Home > News & Events > Cancer Currents Blog

## How Does COVID-19 Affect People with Cancer? NCCAPS Will Help Find Out

Subscribe

May 21, 2020, by James H. Doroshow, M.D.

With the sudden explosion of the COVID-19 pandemic, we are all living with a great deal of fear, uncertainty, and anxiety. As an oncologist and cancer researcher, I know that those feelings are heightened for many people with cancer.

People with cancer are already facing the shock of a cancer diagnosis, the tribulations that accompany treatment, or the stress of survivorship. On top of that, we're learning that people with cancer may be at higher risk of severe illness from COVID-19 because their cancer, or its treatment, has left them more vulnerable to complications.



NCI has launched a study called NCCAPS that will help scientists answer questions about COVID-19's impact on cancer patients and cancer's impact on the course of COVID-19.

Credit: iStock

810

TRIAL SITES  
ACTIVATED  
IN

49

STATES AND  
PUERTO RICO  
*No site in WV.*

283

PATIENTS  
SCREENED

224

ENROLLED



**Norman E. Sharpless** is director of the U.S. National Cancer Institute, Bethesda, MD, USA. norman.sharpless@nih.gov

## COVID-19 and cancer

**W**ith the spread of coronavirus disease 2019 (COVID-19), countries and states have instituted lockdowns. These decisions have been difficult and are sometimes described as benefiting the public health at the expense of the economy. Fear of contracting the coronavirus in health care settings has dissuaded people from screening, diagnosis, and treatment for non-COVID-19 diseases. The consequences for cancer outcomes, for example, could be substantial. What can be done to minimize this effect?

Cancer is a complex set of diseases whose prognosis are influenced by the timing of diagnosis and intervention. In general, the earlier one receives cancer treatment, the better the results. There already has been a steep drop in cancer diagnoses in the United States since the start of the pandemic, but there is no reason to believe the actual incidence of cancer has dropped. Cancers being missed now will still come to light eventually, but at a later stage ("upstaging") and with worse prognoses. At many hospitals, so-called "elective" cancer treatments and surgeries have been deprioritized to preserve clinical capacity for COVID-19 patients. For example, some patients are receiving less intense chemotherapy and/or radiotherapy, and in other cases, patients' operations to remove a newly detected tumor are being delayed. There can be no doubt that the COVID-19 pandemic is causing delayed diagnosis and suboptimal care for people with cancer.

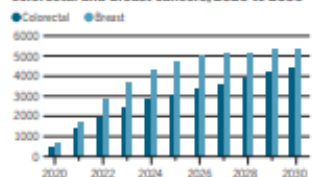
What will be the likely impact of the pandemic on cancer mortality in the United States? Modeling the effect of COVID-19 on cancer screening and treatment for breast and colorectal cancer (which together account for about one-sixth of all cancer deaths) over the next decade suggests almost 10,000 excess deaths from breast and colorectal cancer deaths; that is, a ~1% increase in deaths from these tumor types during a period when we would expect to see almost 1,000,000 deaths from these two diseases types.\* The number of excess deaths per year would peak in the next year or two. This analysis is conservative, as it does not consider other cancer types, it does not account for the additional nonlethal morbidity from upstaging, and it

assumes a moderate disruption in care that completely resolves after 6 months. It also does not account for regional variations in the response to the pandemic, and these effects may be less severe in parts of the country with shorter or less severe lockdowns.

Beyond clinical care, the COVID-19 pandemic has caused an unprecedented disruption throughout the cancer research community, shuttering many labs and slowing down cancer clinical trial operations. Many scientists and clinicians are pivoting their cancer research activities to study the impact of SARS-CoV-2 on cancer. The scientific community must ensure that this pause is only temporary, because trials are the only way to make progress in developing new therapies for cancer. Given the

long timeline between basic cancer research and changes to cancer care, the effects of pausing research today may lead to slowdowns in cancer progress for many years to come.

**Modeled cumulative excess deaths from colorectal and breast cancers, 2020 to 2030\***



address this challenge (see [www.cancer.gov](http://www.cancer.gov)). The NCI has worked with the U.S. Food and Drug Administration to increase flexibility and support for clinical trials during the pandemic. For example, allowances have been made to accept "remote" informed consent, and other protocol deviations. In addition, the NCI has announced several new clinical trials and funding opportunities aimed at addressing the relationship between COVID-19 and cancer. Of particular note is the NCI COVID-19 in Cancer Patients Study, a prospective longitudinal study that will collect blood samples, imaging, and other data to understand how COVID-19 affects cancer patients.

Clearly, postponing procedures and deferring care as a result of the pandemic was prudent at one time, but the spread, duration, and future peaks of COVID-19 remain unclear. However, ignoring life-threatening non-COVID-19 conditions such as cancer for too long may turn one public health crisis into many others. Let's avoid that outcome.

—Norman E. Sharpless

\*See supplementary materials ([science.sciencemag.org/content/368/6407/1290/suppl/DC1](https://science.sciencemag.org/content/368/6407/1290/suppl/DC1)).

10.1126/science.abd3377

Downloaded from <https://science.sciencemag.org/> on June 22, 2020

## The Washington Post

By Laurie McGinley

June 18, 2020 at 7:30 p.m. EDT

# Nation's cancer chief warns delays in cancer care are likely to result in thousands of extra deaths in coming years

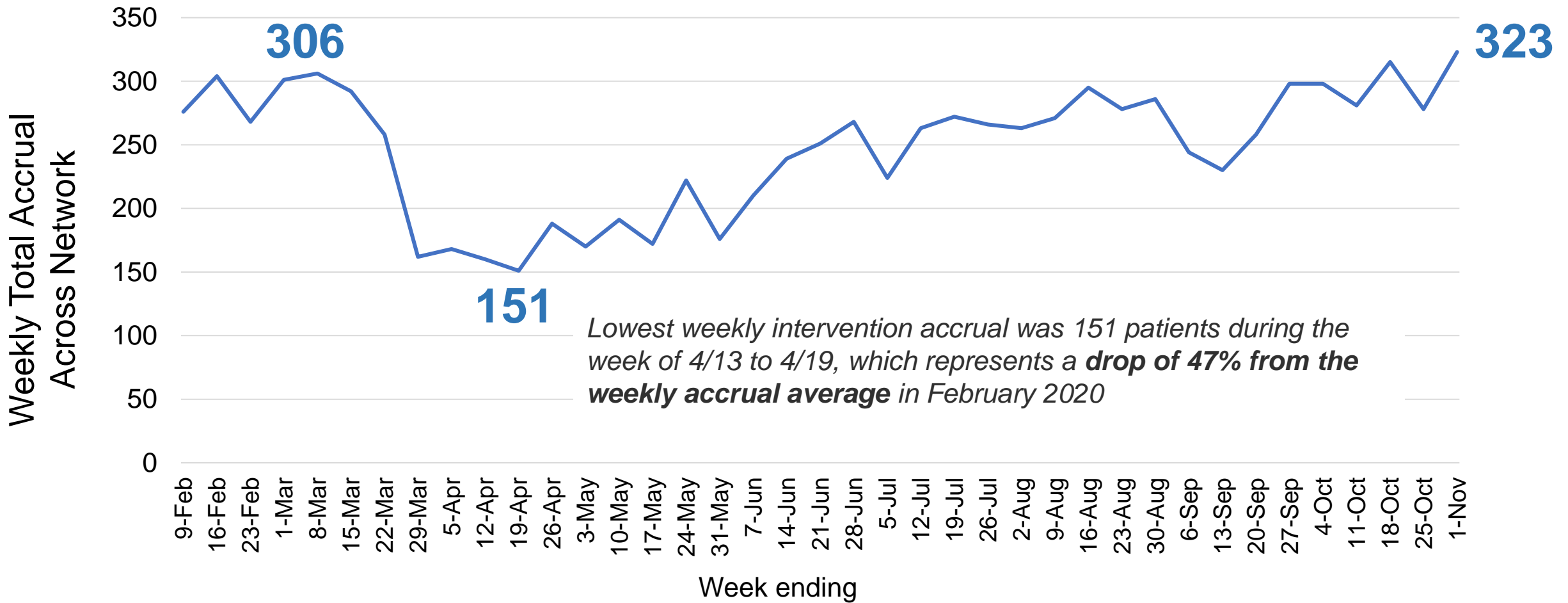
## STAT

# Ignoring cancer care now may trade one public health crisis — Covid-19 — for another, NCI chief warns

By ELIZABETH COONEY @cooney\_liz / JUNE 19, 2020

# NCTN Trial Accrual:

## Weekly totals 2/3/20 to 11/1/20



# New CTAC *Ad Hoc* Working Group on Cancer Screening Trials

## **Charge**

*To advise on the real-world impact of the COVID-19 pandemic on screening trials; on scientific questions that may be answered; and on strategies and timeline for their completion.*

- Approved by NCAB in October
- First virtual meeting November 18
- **Chair:** Nancy E. Davidson, M.D.
- Will consider TMIST first

# New CTAC *Ad Hoc* Working Group on Cancer Screening Trials

**Chair: Nancy E. Davidson, M.D.**

Otis W. Brawley, M.D.

Abenaa M. Brewster, M.D., M.H.S.

Susan G. Braun

Deborah Watkins Bruner, R.N., Ph.D.

Ruth Etzioni, Ph.D.

Herbert Kressel, M.D.

Terry P. Mamounas, M.D., M.P.H.

Larry Norton, M.D.

Augusto C. Ochoa, M.D.

Electra D. Paskett, Ph.D.

Gloria M. Petersen, Ph.D.

Edward Sickles, M.D.

Larissa Korde, M.D.

Worta McCaskill-Stevens, M.D., M.S.

Sheila A. Prindiville, M.D.

# Telehealth & Cancer Care Delivery



## Request for Information – July 2020

Scientific Gaps and Research Needs Related to Delivery of Cancer-related Care via Telehealth (Notice NOT-CA-20-080)

## Telehealth and Cancer Care Delivery Webinar Series

COVID-19 Pandemic: Natural Experiment in Rural Cancer Care Telehealth Capacity

- *October 30. Event recording available soon.*

Self-Management to Optimize Survivorship Care and Outcomes in Lung and Colorectal Cancer

- *February 4, 2021*

Additional events to follow; [healthcaresdelivery.cancer.gov/](https://healthcaresdelivery.cancer.gov/)

# Lung cancer mortality

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## The Effect of Advances in Lung-Cancer Treatment on Population Mortality

Nadia Howlader, Ph.D., Gonçalo Forjaz, D.V.M., Meghan J. Mooradian, M.D.,  
Rafael Meza, Ph.D., Chung Yin Kong, Ph.D., Kathleen A. Cronin, Ph.D.,  
Angela B. Mariotto, Ph.D., Douglas R. Lowy, M.D., and Eric J. Feuer, Ph.D.

AUGUST 13, 2020

— AMONG U.S. MEN —

DEATHS FROM THE  
MOST COMMON TYPE OF  
LUNG CANCER

FELL

↓ 3.2%

EACH YEAR FROM 2006 TO 2013

THEN FELL

↓ 6.3%

EACH YEAR FROM 2013 TO 2016



# Cancer Grand Challenges – NCI/CRUK Partnership



- **9 Grand Challenges** inviting **novel ideas** from **multidisciplinary research teams** from around the world that offer the potential to make bold advances in cancer research and improve outcomes for people affected by cancer.
- **Expressions of interest accepted until April 22, 2021**



**Visit [cancer.gov](https://cancer.gov)**

# NCI Equity & Inclusion Program

## Equity Council

**Enhancing  
Research to  
Address Cancer  
Health  
Disparities**

**Ensuring  
Diversity of  
Thought and  
Background in  
the Cancer  
Research  
Workforce**

**Promoting an  
Inclusive and  
Equitable  
Community at  
NCI**

# FIRST Faculty Institutional Recruitment for Sustainable Transformation

- Foster sustainable institutional culture change
- Promote **inclusive excellence** by hiring a diverse cohort of new faculty
- Support faculty development, mentoring, sponsorship, and promotion

- NIH Common Fund Initiative  
[commonfund.nih.gov/first](https://commonfund.nih.gov/first)
- 12 staggered awards: 4 per year x 3 years
- Highly Resourced Institutions (HRI) and Limited-Resourced Institutions (LRI) may apply independently or in partnership
- Develop and implement faculty cohort models for the simultaneous hiring of a diverse group of research faculty
- Programming to reduce isolation, increase community building, and foster career advancement
- See **NOT-RM-20-023**

# The National Cancer Act — A Watershed Moment

*The Act united patients, scientists, doctors, industry and government all under one vision.*

**Accelerated research** on prevention, screening, diagnosis, and treatment of cancer.

**Increased support for basic research**, providing a critical underpinning to our cancer progress.

**Created the nation's clinical trials network**, leading to practice-changing trials for patients.

**Established the NCI-designated Cancer Centers Program** of world-class institutes, driving research and patient care.

**Focused conversation on prevention** as part of the cancer continuum.

**Created Frederick National Lab**, the first government lab for targeted, high priority cancer projects.

**Built SEER** and improved cancer registries.

# Commemorating the 50th Anniversary of the National Cancer Act

To ignite enthusiasm for scientific research and funding to continue the fight against cancer and inspire the next generation of diverse talent

*The 50th anniversary of the National Cancer Act is an opportunity to commemorate the tremendous progress made in cancer research, consider the needs that remain, and affirm our unwavering commitment to people with cancer.*

**NOTHING WILL STOP US**

**NOTHING WILL  
STOP US 50 YEARS**

NATIONAL CANCER ACT

# Discussion