NCI Director's Report

Norman E. Sharpless, M.D.

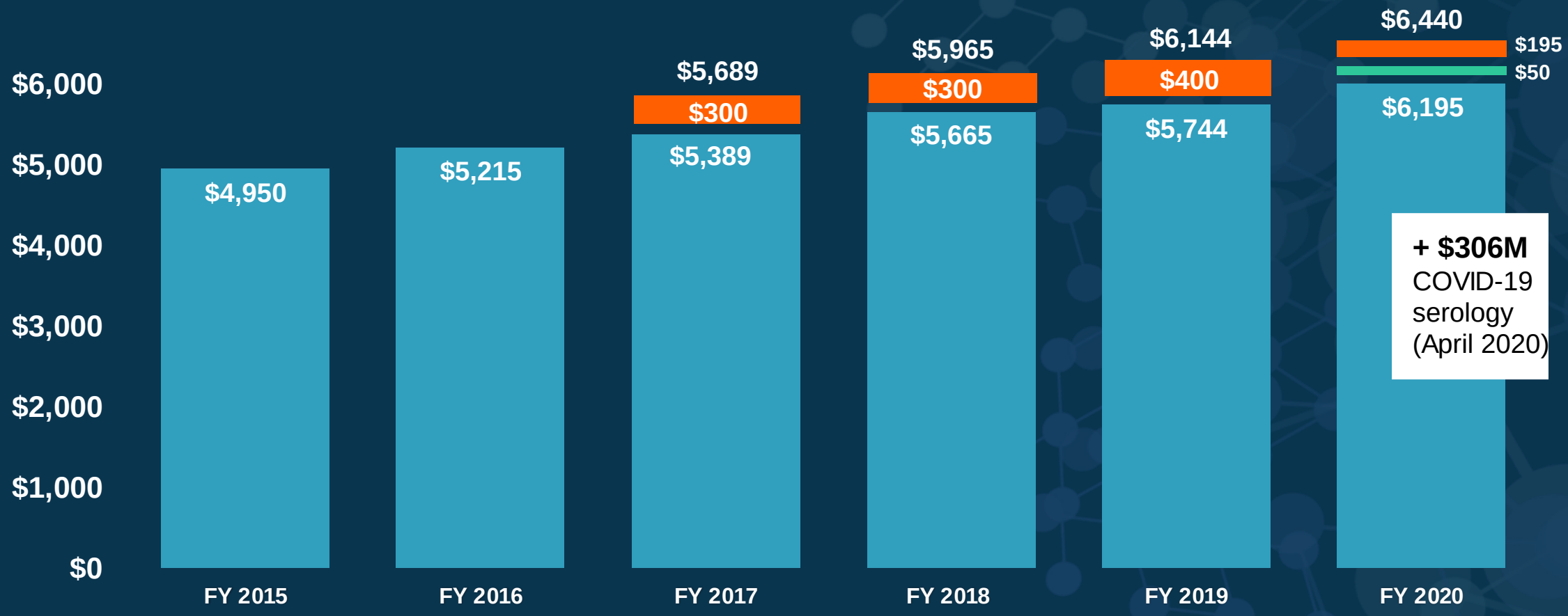
3rd Virtual Joint Meeting of NCI Board of Scientific Advisors & National Cancer Advisory Board

December 1, 2020

@NCIDirector
@TheNCI

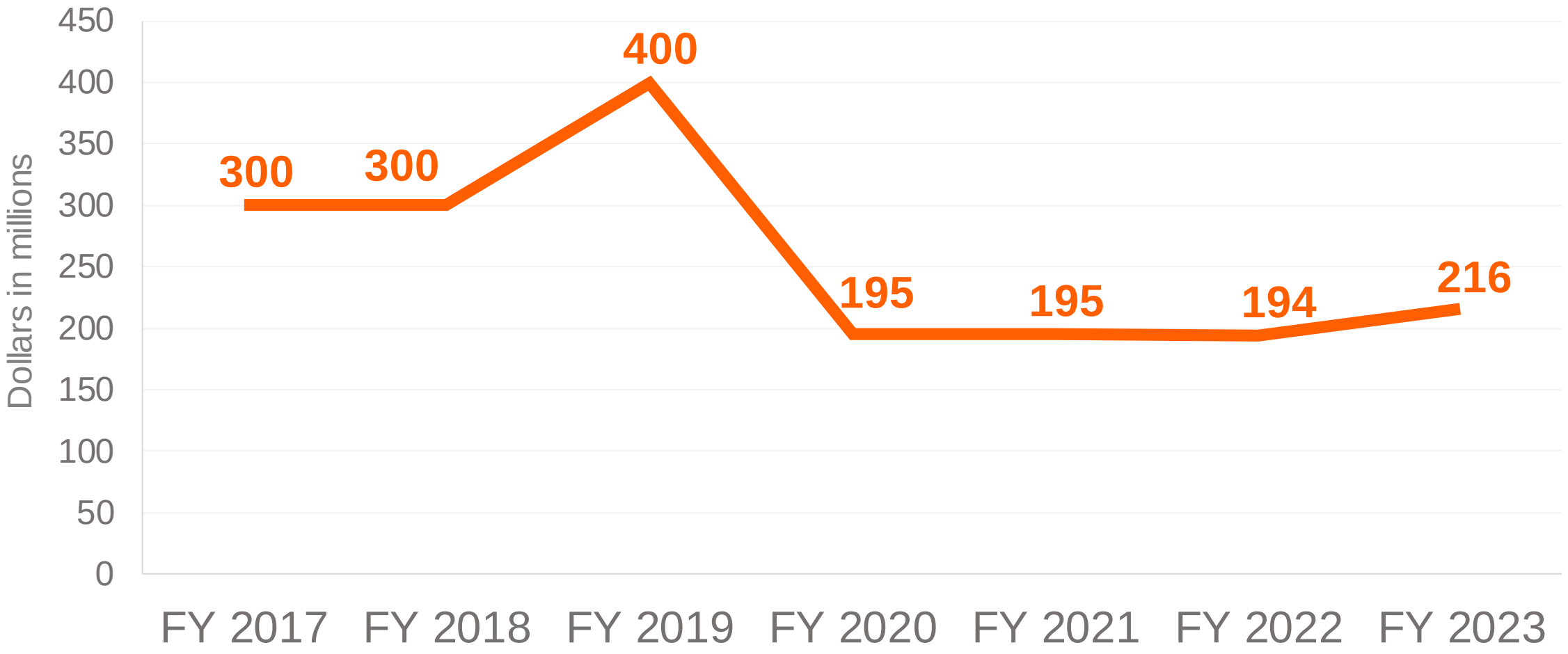
NCI Appropriations FY 2015 – 2020 (in millions)

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



Cancer Moonshot Funding

Authorized Under the 21st Century Cures Act (dollars in millions)

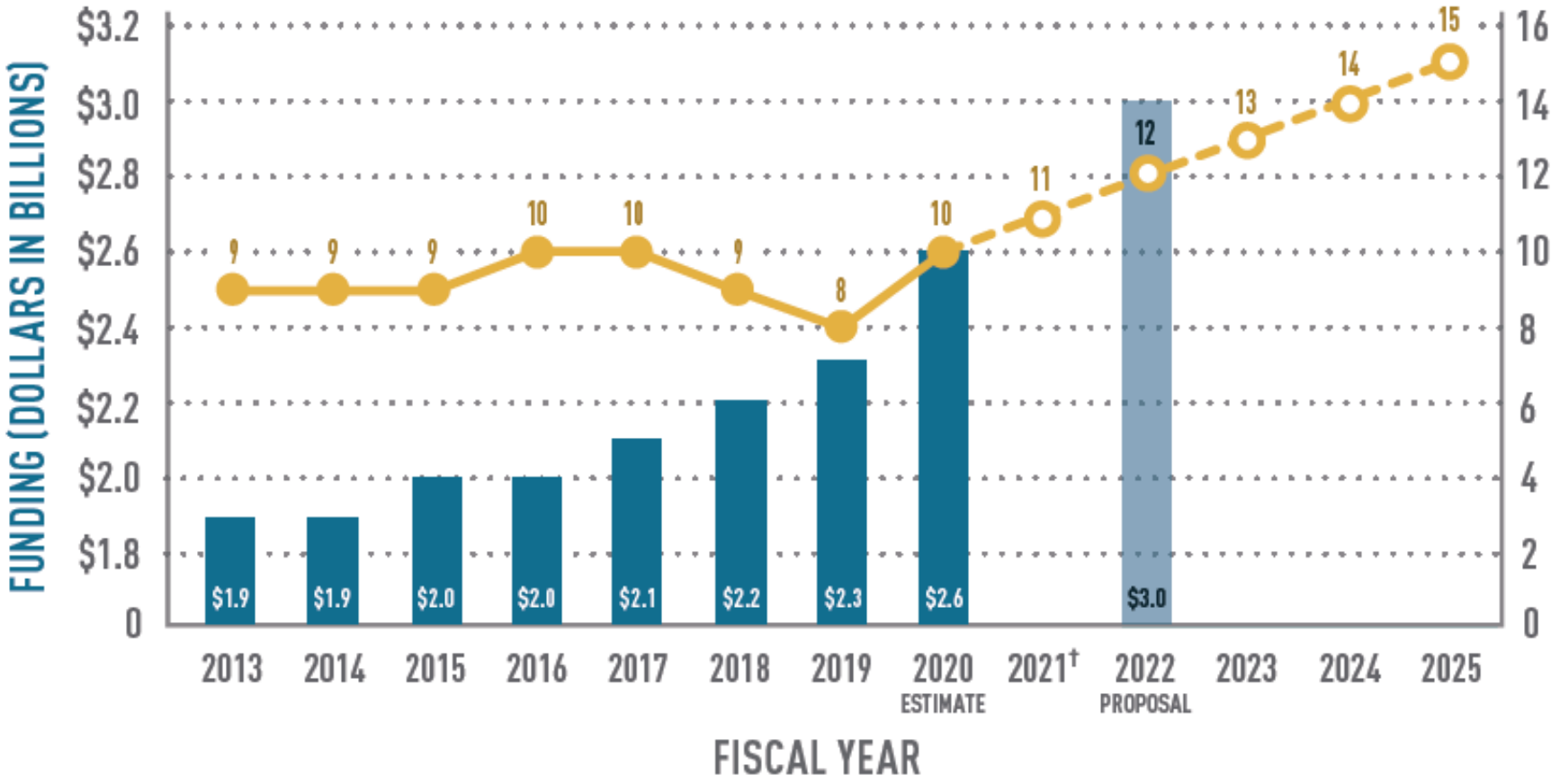


ANNUAL PLAN & BUDGET PROPOSAL

Fiscal Year 2022

cancer.gov/research/annual-plan

NCI Research Project Grants (RPG) Funding and R01 Paylines



RPG Funding

Proposed RPG Funding

R01 Payline

R01 Payline Goal

- RPG funding levels exclude small business grant set-asides.
- † FY 2021 appropriation not yet determined.

Note: The left scale displays funding for all NCI Research Project Grants (RPGs), including R01 RPGs. Therefore, the left scale does not represent the actual future funding needed to achieve the future R01 payline on the right scale.

NCI Interim Paylines: FY 2021 Competing Grants

GRANT TYPE	INTERIM PAYLINE
R01 Grants for Established and New Investigators	9th Percentile
R01 Grants for Early-Stage Investigators (ESIs)	14th Percentile
R21 Exploratory Grants	9th Percentile

NCI Bottom Line: A Blog about Grants and More

Subscribe

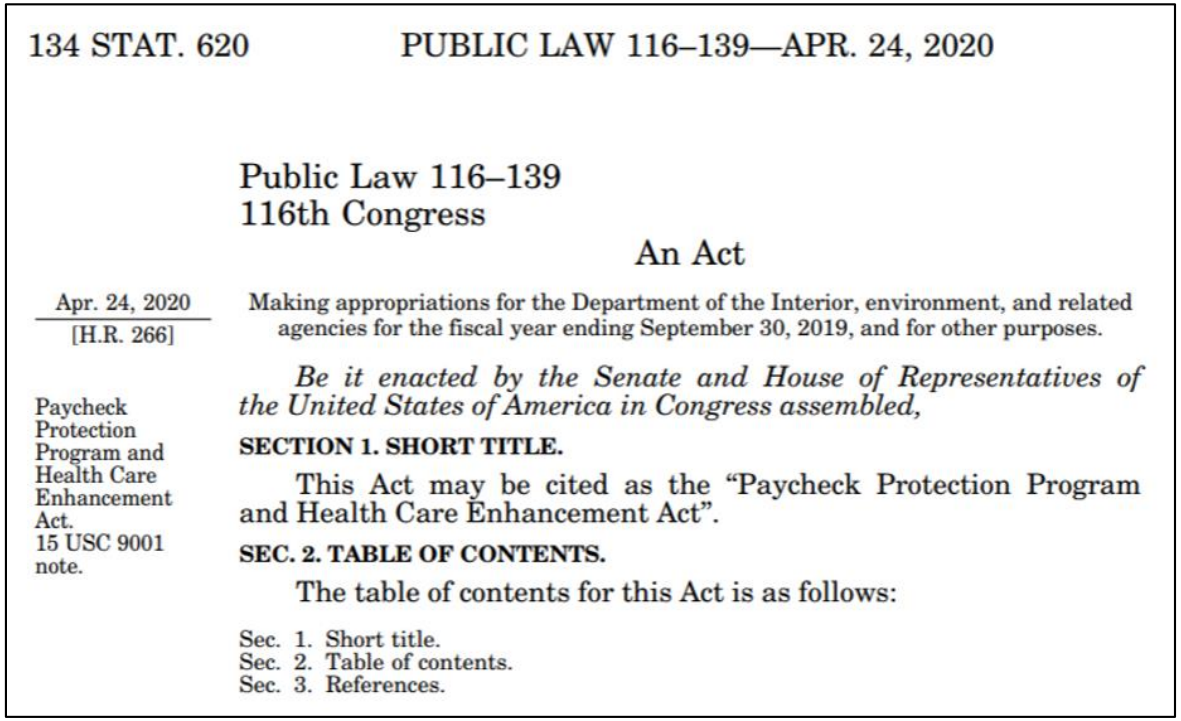
NCI's New Fiscal Year Brings Old Fiscal Challenges

November 3

www.cancer.gov/grants-training/nci-bottom-line-blog

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

Apr. 24, 2020
[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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Paycheck Protection Program and Health Care Enhancement Act.
15 USC 9001 note.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Paycheck Protection Program and Health Care Enhancement Act".

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

Sec. 1. Short title.
Sec. 2. Table of contents.
Sec. 3. References.

SARS-CoV-2 Serology Validation Program: Overview

Collaborative effort between NCI, NIAID, FDA, CDC, BARDA and several academic groups

GOAL: Performance evaluation of ELISA assays, Lateral Flow Devices and Automated Chemiluminescent Immunoassays to assist the FDA in determining suitability for EUA approval

Evaluation Panel: Production and Qualification

1. **Sample acquisition**
2. **Sample Characterization at multiple dilutions**

CDC Assays:

- SARS-CoV-2 Spike IgG and IgM ELISA
- SARS-CoV-2 Spike Total Ig

FNLCR Assays:

- SARS-CoV-2 Spike IgG and IgM ELISA
- SARS-CoV-2 Spike Total Ig
- SARS-CoV-2 RBD IgG

Evaluation Panel

Positive samples:

- 30 PCR+ patient's sera

Negative samples:

- 80 pre-pandemic negative controls plasma, including 10 HIV-positive samples

Sample Characterization: CDC and FNLCR

Commercial Assay Performance Evaluation

1. Entities submit their serology assays for evaluation by this program
2. Testing is done at FNLCR according to corresponding protocol using evaluation panels
3. Data is sent to FDA
4. Sensitivity and Specificity are determined

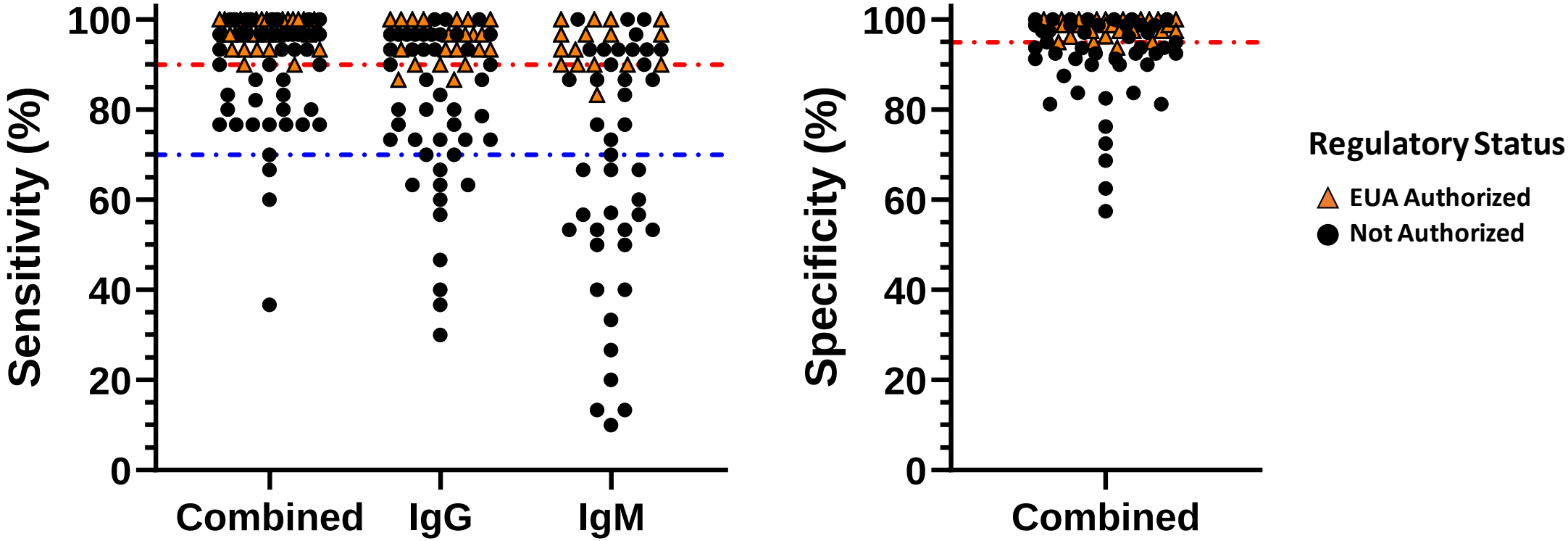
FDA uses the antibody test performance in regulatory decision making and makes those decisions publicly available

SARS-CoV-2 Serology Validation

Progress to date *(as of October 15)*

282 commercial assays delivered to NCI/FNL	Performance data for **104** commercial assays delivered to FDA	**56** assays granted EUA by FDA (~25 evaluated by NCI)

Sensitivity and Specificity by Regulatory Status

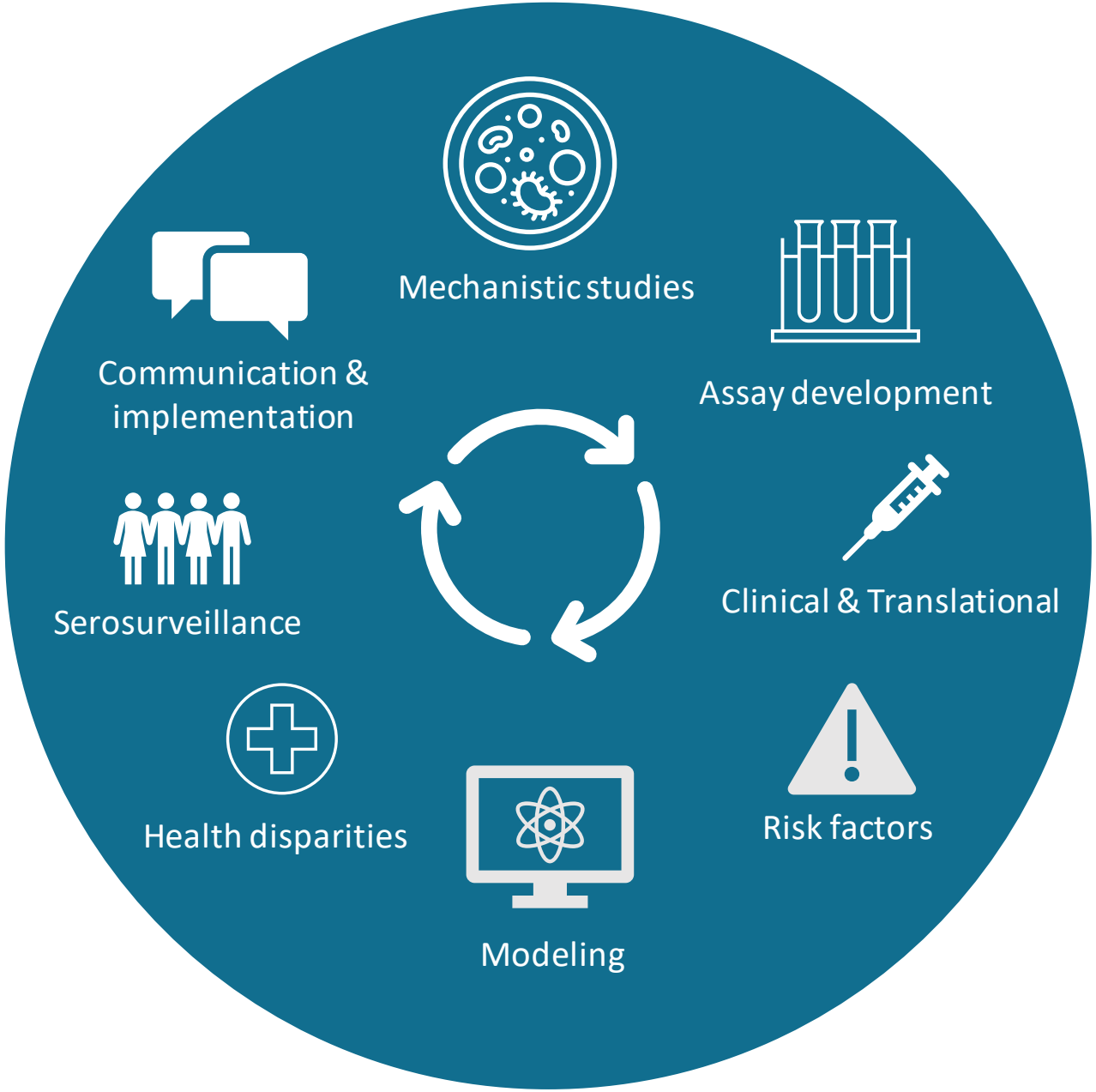


Dotted lines define threshold values for acceptable performance in FDA EUA template

- Sensitivity Red line is for IgG (90%)
- Sensitivity Blue line is for IgM (70%)
- Specificity Red line is for Combined (95%)

The Serological Sciences Network (SeroNet)

SeroNet supports a broad range of serological sciences research to advance our understanding of all aspects of the immune response to SARS-CoV-2.



SeroNet Serological Sciences Network

- Grants (U54s and U01s)
- Contracts (Capacity Building Centers)
- National Laboratory

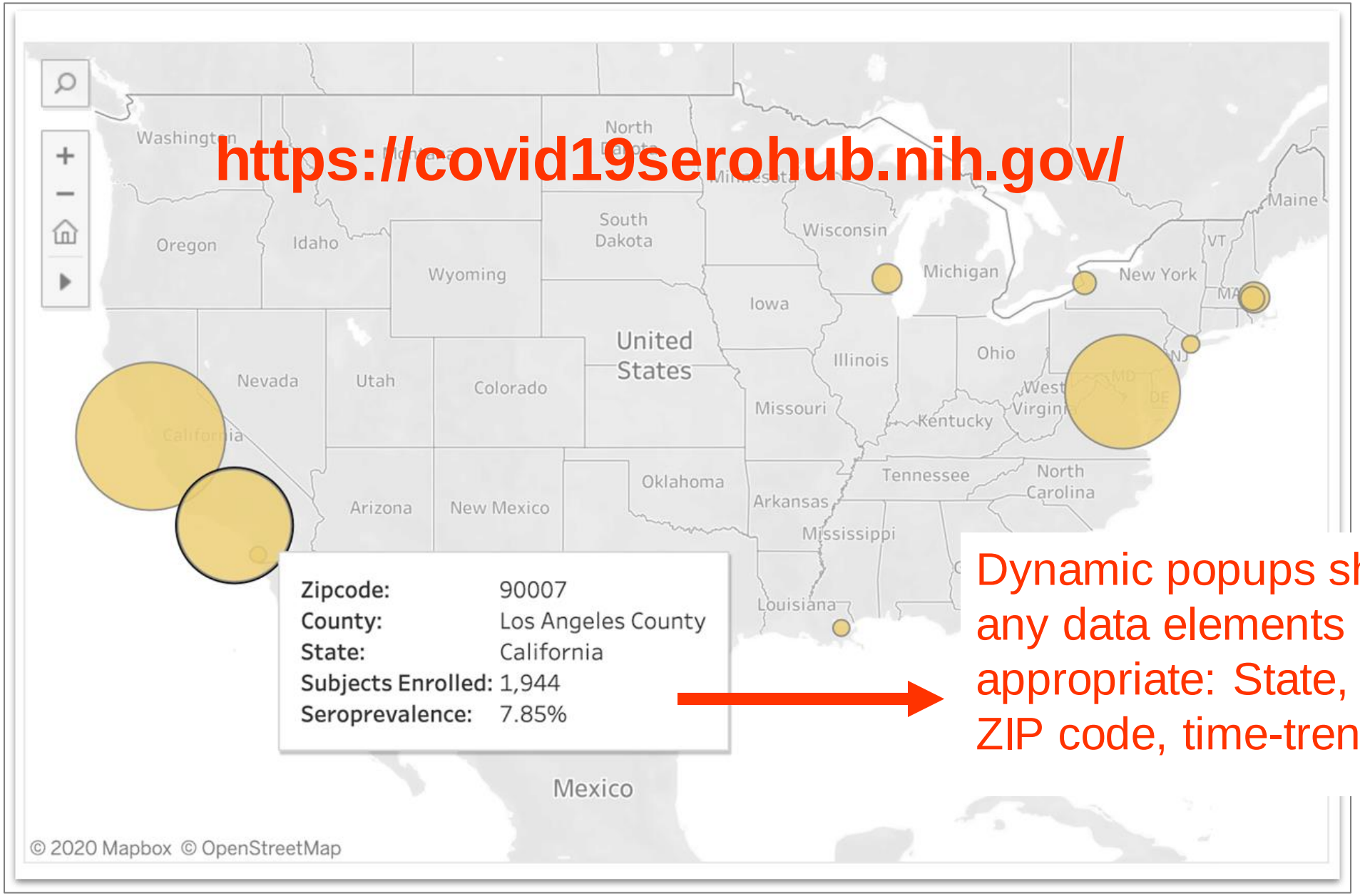
Launched October 8

SARS-CoV-2 Serology Study Dashboard

- Effort began in early June at the request of HHS, CDC, and NIAID to develop a data warehouse & dashboard for tracking SARS-CoV-2 seroprevalence and other US-based serology studies
- Builds on FNL expertise in warehouse and dashboard development for other NCI resources

Key features

- Publicly accessible data warehouse to systematically document and track SARS-Cov-2 serology studies and associated test results
- Tracking dashboard to visualize SARS-Cov-2 serology data and present results overall and by key strata



Dynamic popups showing any data elements deemed appropriate: State, county, ZIP code, time-trends

NCI COVID-19 in Cancer Patients Study (NCCAPS)

NIH NATIONAL CANCER INSTITUTE

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

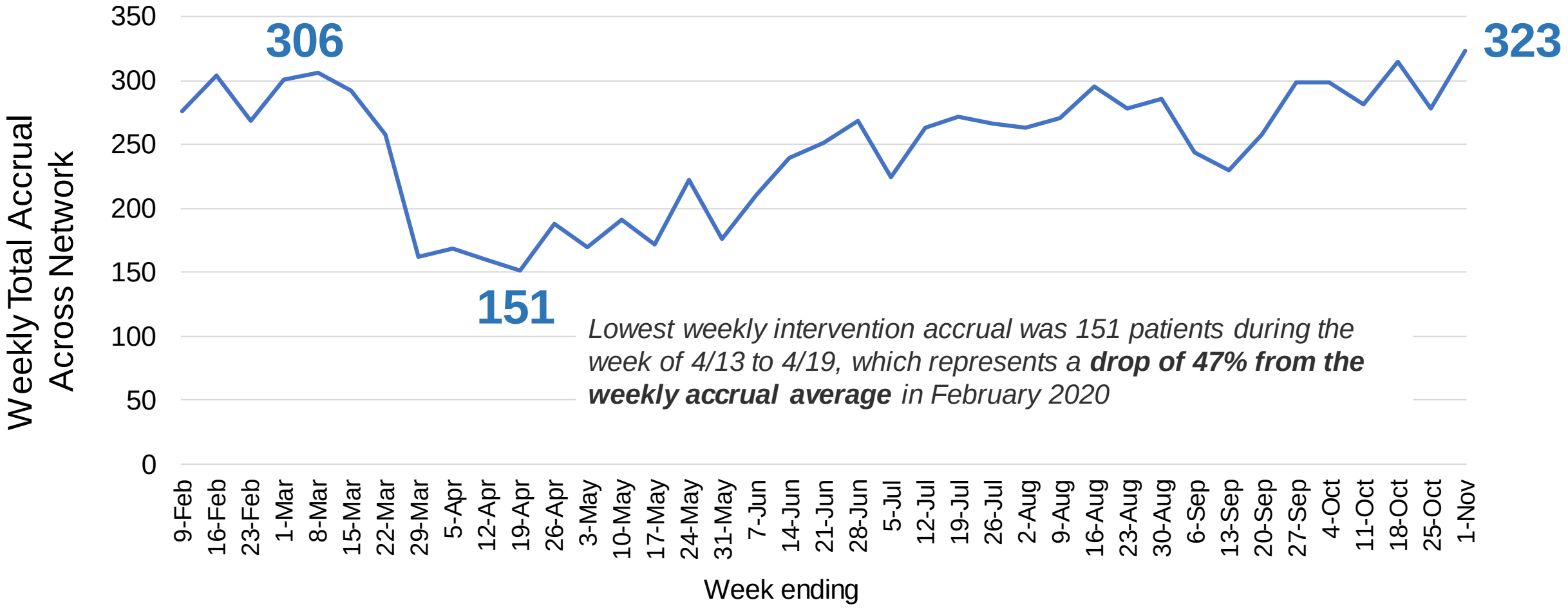
PATIENTS SCREENED

224

ENROLLED

Figures as of October 29, 2020.

NCTN Trial Accrual:
Weekly totals 2/3/20 to 11/1/20

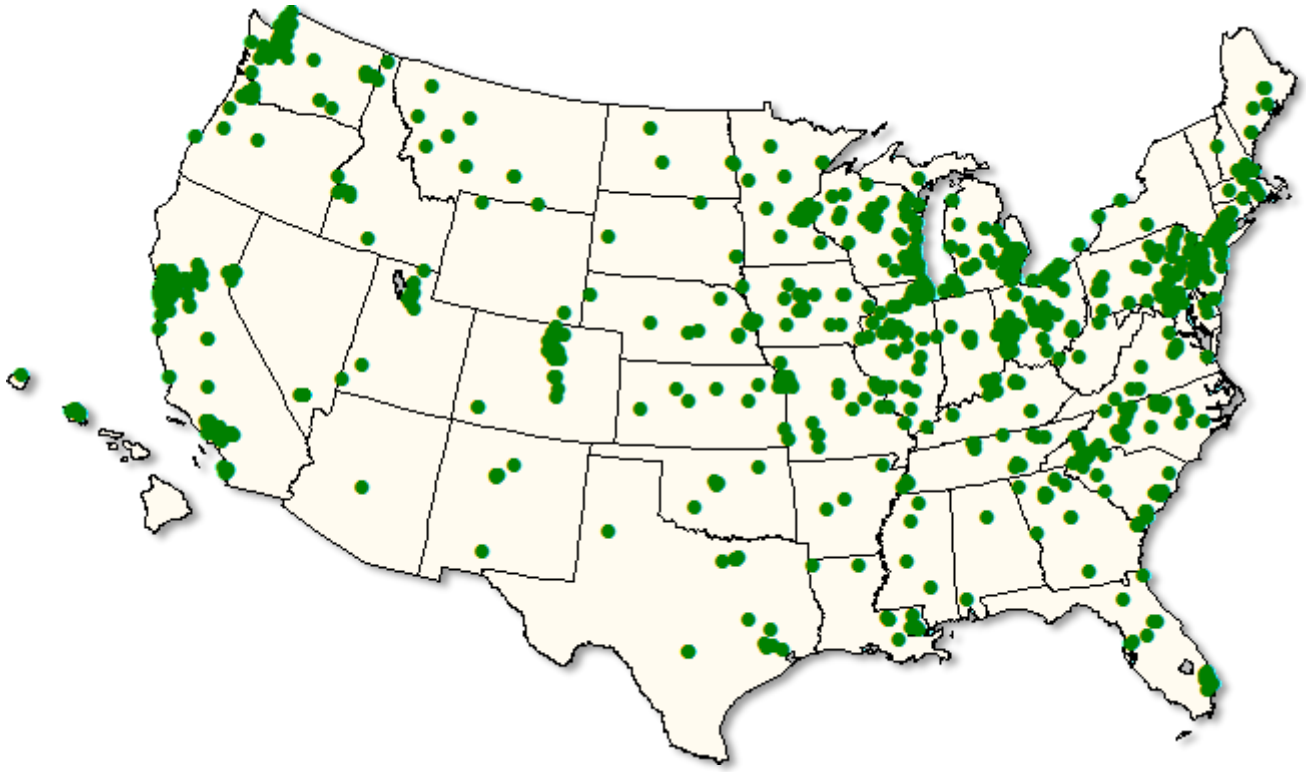


Study of “exceptional responders” yields clues to cancer and potential treatments

NCI News Release
November 19, 2020

For **26 of the 111 (24%)** patients, researchers were able to identify molecular features that could potentially explain exceptional responses to treatment, such as the **co-occurrence of multiple rare genetic changes in the tumor genome** or the **infiltration of the tumor with certain types of immune cells.**

NCI Molecular Analysis for Therapy Choice (NCI-MATCH)



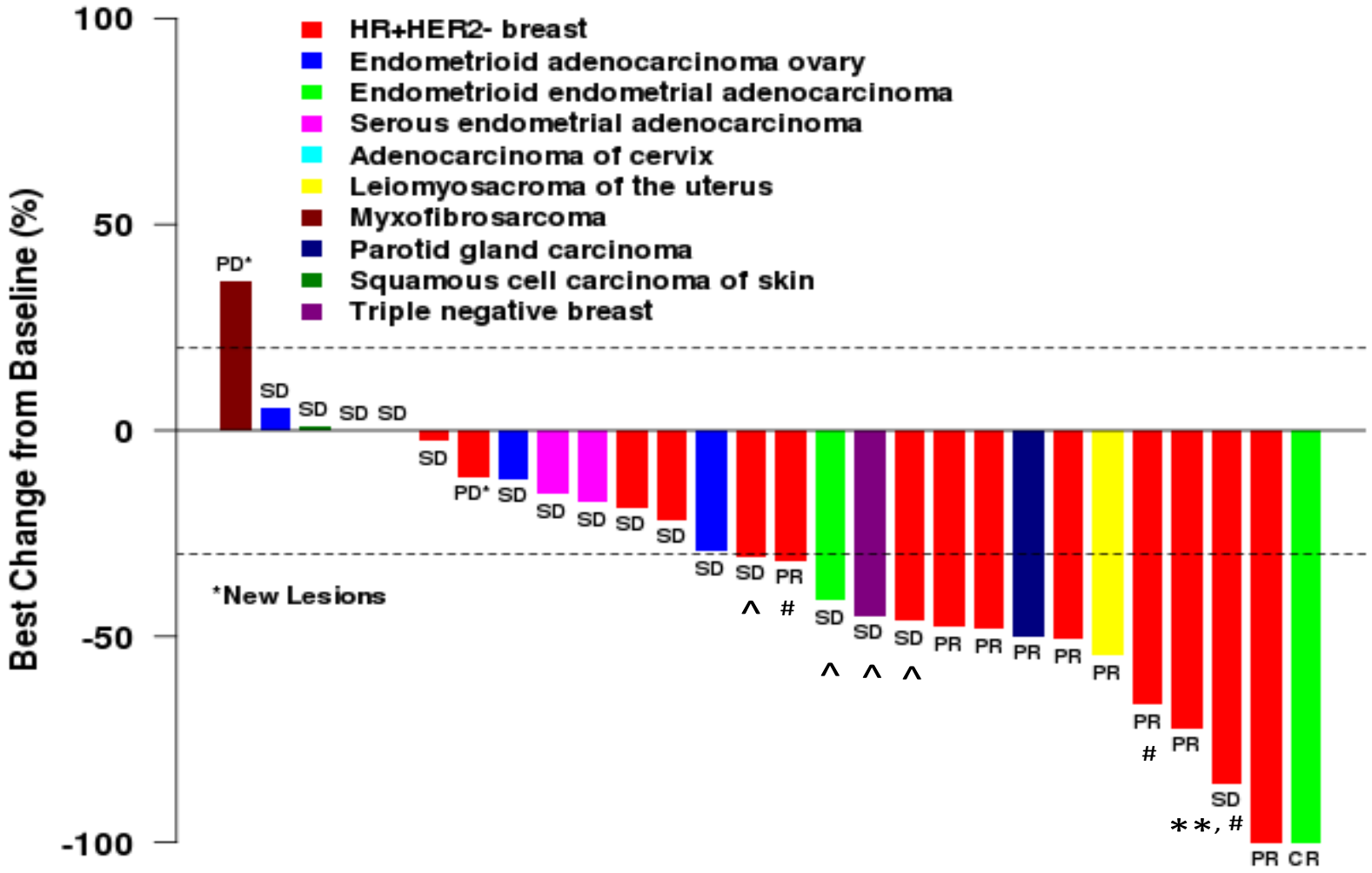
Precision oncology trial to explore treating patients based on the molecular profiles of their tumors

Over 1100 sites in U.S. across NCTN and NCORP

Select NCI MATCH Treatment Arms with Findings

Drug	Target	Arm	ORR		Publication/Status
Ado-trastuzumab emtansine	HER2 amplifications	Q	8%		Jhaveri KL, *Ann Onc,* online ahead of print 08-27-19
Afatinib	HER2 activating mutations	B	2.7%		Bedard PL, AACR 2019 Annual Mtg
AZD1775	BRCA1 or BRCA2 mutations	Z1I	3.2%		Kummar S, AACR 2019 Annual Mtg
AZD4547	FGFR pathway aberrations	W	8%		Chae YK, *JCO,* ASCO 2018 Annual Mtg
Capivasertib	AKT mutations	Y	23%	☆	Kalinsky KM, EORTC-NCI-AACR 2018 Mtg
GSK2636771	PTEN expression or loss by IHC PTEN mutations/deletions	P N	0% 5%		Janku FM, *Ann Oncol*, ESMO 2018 Mtg
Nivolumab	dMMR status	Z1D	24%	☆	Azad NS, J Clin Oncol, 38 (3), 214-222 2020 Jan 20
Palbociclib	CCND1, 2, or 3 amplifications and Rb protein expression by IHC	Z1B	0%		Clark AS, AACR 2019 Annual Mtg
Taselisib	PIK3CA mutations	I	0%		Krop IE, *JCO*, ASCO 2018 Annual Mtg
Trametinib + Dabrafenib	BRAF V600E or V600K mutations	H	33%	☆	Salama AKS, ASCO 2019 Annual Mtg

Arm Y: Response to capivasertib in patients with AKT1 E17K mutant tumors



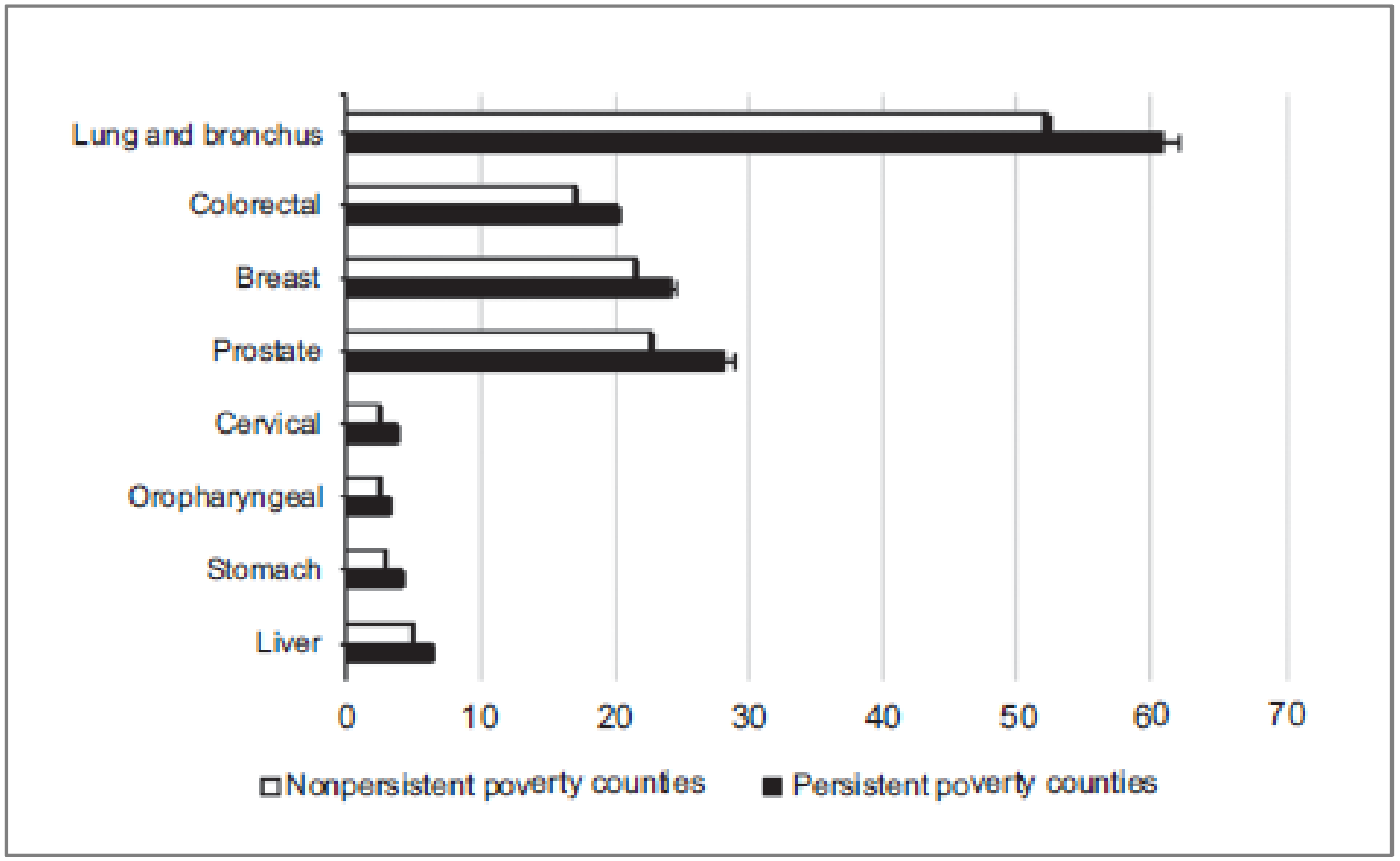
What's next for NCI-MATCH

- 8 arms of MATCH are still accruing.
- NCI-COG Pediatric MATCH is ongoing and accruing well (11 arms accruing).
- Several correlative studies are planned or underway using samples and data collected as part of MATCH,
- We are planning next round of MATCH studies (e.g. Myelo-MATCH and Combo-MATCH) and expect these to open in 2021.
- MATCH has permanently changed cancer clinical trials: basket trials are here to stay.

Persistent Poverty and Cancer Mortality Rates: An Analysis of County-Level Poverty Designations

Cancer Epidemiology, Biomarkers & Prevention
2020 Oct 29 (10): 1949-1954.

Jennifer L. Moss, Casey N. Pinto, Shobha Srinivasan, Kathleen A. Cronin and Robert T. Croyle



Cancer Grand Challenges

Expressions of interest accepted until **April 22, 2021**

CANCER RESEARCH UK | NIH NATIONAL CANCER INSTITUTE

cancer.gov

cancergrandchallenges.org

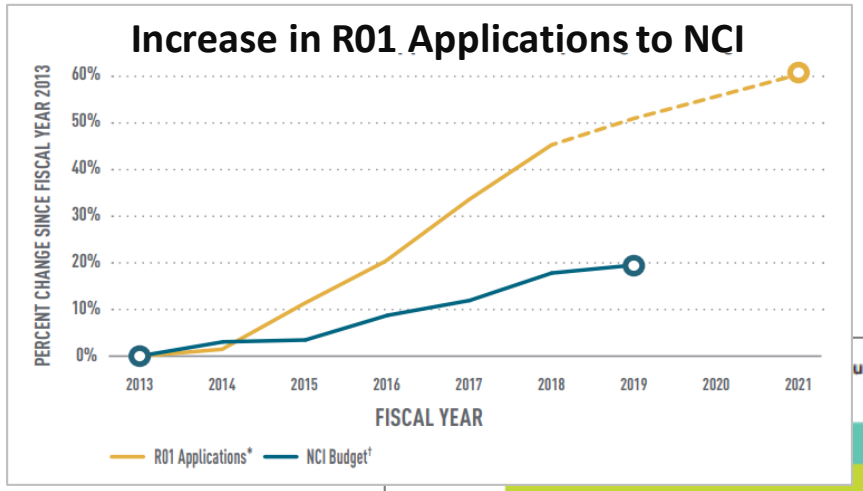
- Understand how cells and tissues maintain "normal" phenotypes while harboring oncogenic mutations and how they transition to become a tumor
- Determine the potential benefits and risks of e-cigarette use
- Develop novel therapies to target unique features in solid tumors in children
- Systematically deliver macromolecules to intracellular targets for therapeutic benefit in cancer
- Understand and exploit senescence to improve cancer treatment
- Determine how inflammation causes cancer
- Identify and target dormant cancer cells
- Understand the biology of extrachromosomal DNA (ecDNA) generation and action and develop approaches to target these mechanisms in cancer
- Understand and reverse cachexia and declining performance status in cancer patients

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
- 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-20-022, -023**

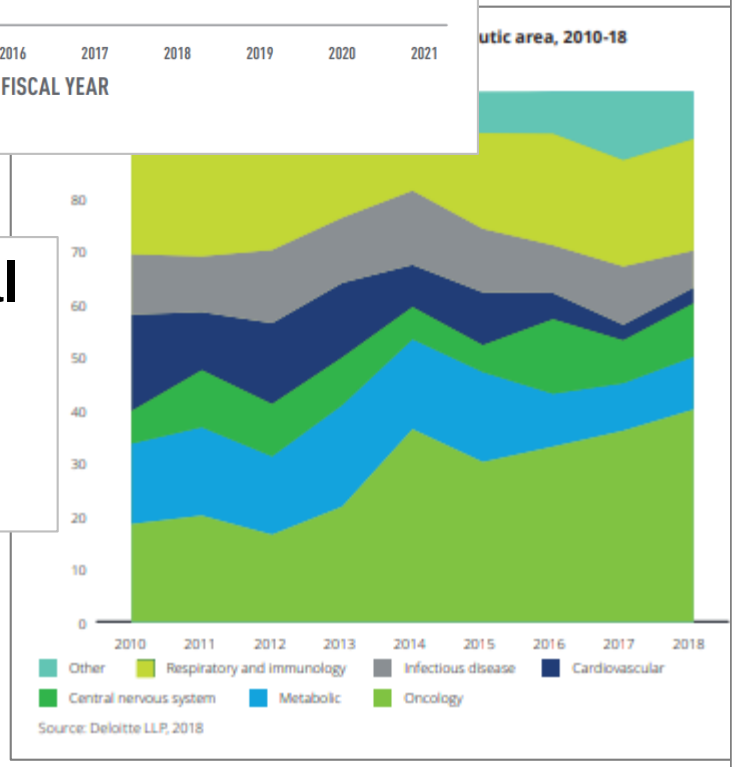
Remarkable progress in cancer research and outcomes

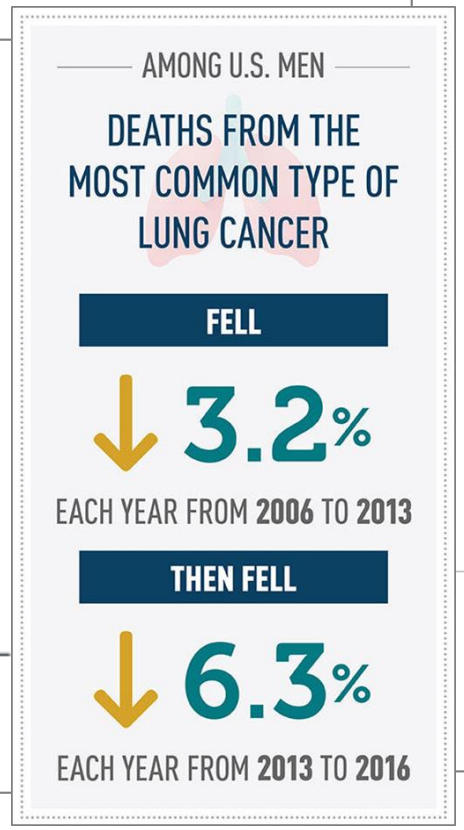


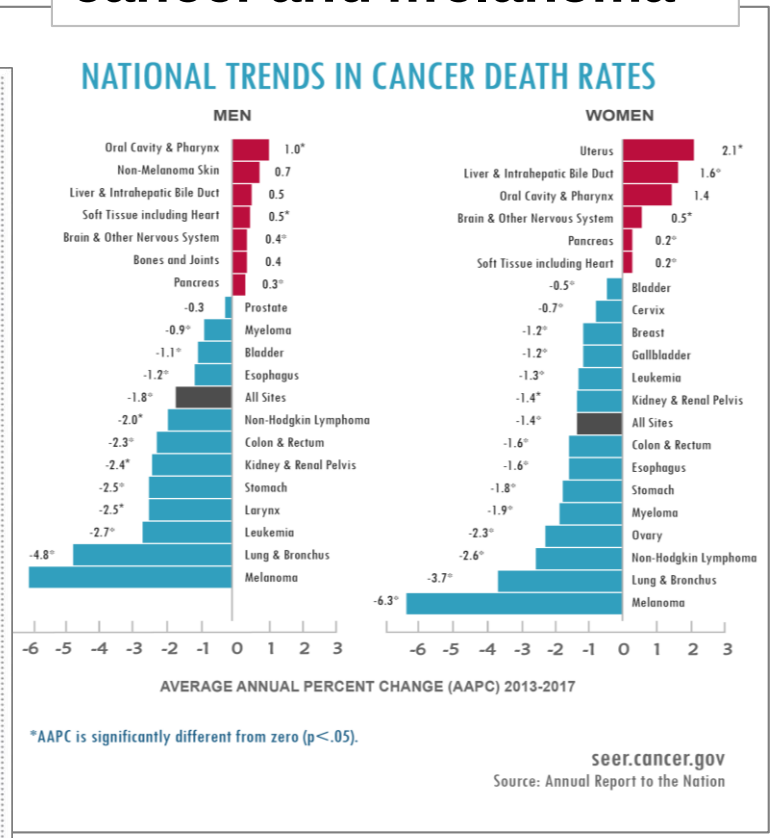
Record numbers of cancer drug approvals by FDA in 2018 & 2019

Declining cancer mortality, even in lung cancer and melanoma

Pharmaceutical industry investment in cancer drugs



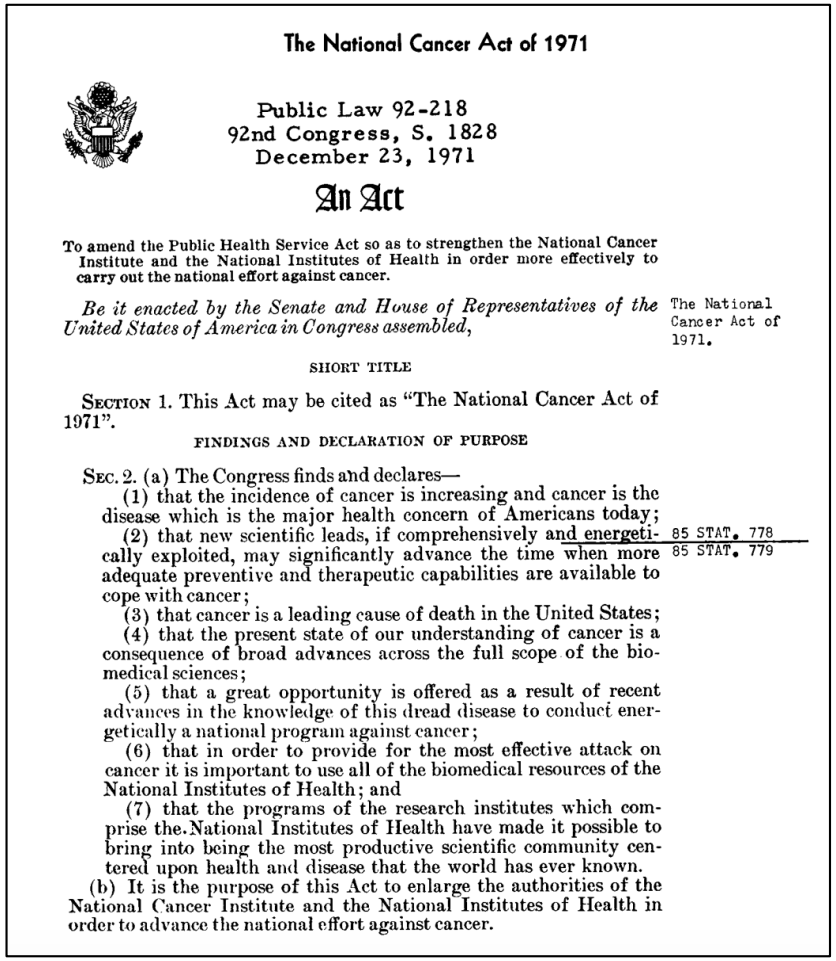




The National Cancer Act — A Watershed Moment

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.
- **Created Frederick National Lab**, the first government lab for targeted, high priority cancer projects.
- **Built SEER** and improved cancer registries.



The National Cancer Act of 1971

Public Law 92-218
92nd Congress, S. 1828
December 23, 1971

An Act

To amend the Public Health Service Act so as to strengthen the National Cancer Institute and the National Institutes of Health in order more effectively to carry out the national effort against cancer.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

The National Cancer Act of 1971.

SHORT TITLE

SECTION 1. This Act may be cited as "The National Cancer Act of 1971".

FINDINGS AND DECLARATION OF PURPOSE

SEC. 2. (a) The Congress finds and declares—

(1) that the incidence of cancer is increasing and cancer is the disease which is the major health concern of Americans today;

(2) that new scientific leads, if comprehensively and energetically exploited, may significantly advance the time when more adequate preventive and therapeutic capabilities are available to cope with cancer;

(3) that cancer is a leading cause of death in the United States;

(4) that the present state of our understanding of cancer is a consequence of broad advances across the full scope of the biomedical sciences;

(5) that a great opportunity is offered as a result of recent advances in the knowledge of this dread disease to conduct energetically a national program against cancer;

(6) that in order to provide for the most effective attack on cancer it is important to use all of the biomedical resources of the National Institutes of Health; and

(7) that the programs of the research institutes which comprise the National Institutes of Health have made it possible to bring into being the most productive scientific community centered upon health and disease that the world has ever known.

(b) It is the purpose of this Act to enlarge the authorities of the National Cancer Institute and the National Institutes of Health in order to advance the national effort against cancer.

85 STAT. 778
85 STAT. 779

50 NATIONAL CANCER ACT 1971-2021

OUR GOAL

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

NOTHING WILL STOP US

NATIONAL CANCER ACT 50 YEARS

50 NATIONAL CANCER ACT 1971-2021

Discussion