

NCI Director's Report

Norman E. Sharpless, M.D.

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

March 16, 2022

@NCIDirector
@TheNCI

New CTAC Members – Welcome!

Gary C. Doolittle, MD – University of Kansas

Robert Mannel, MD – University of Oklahoma

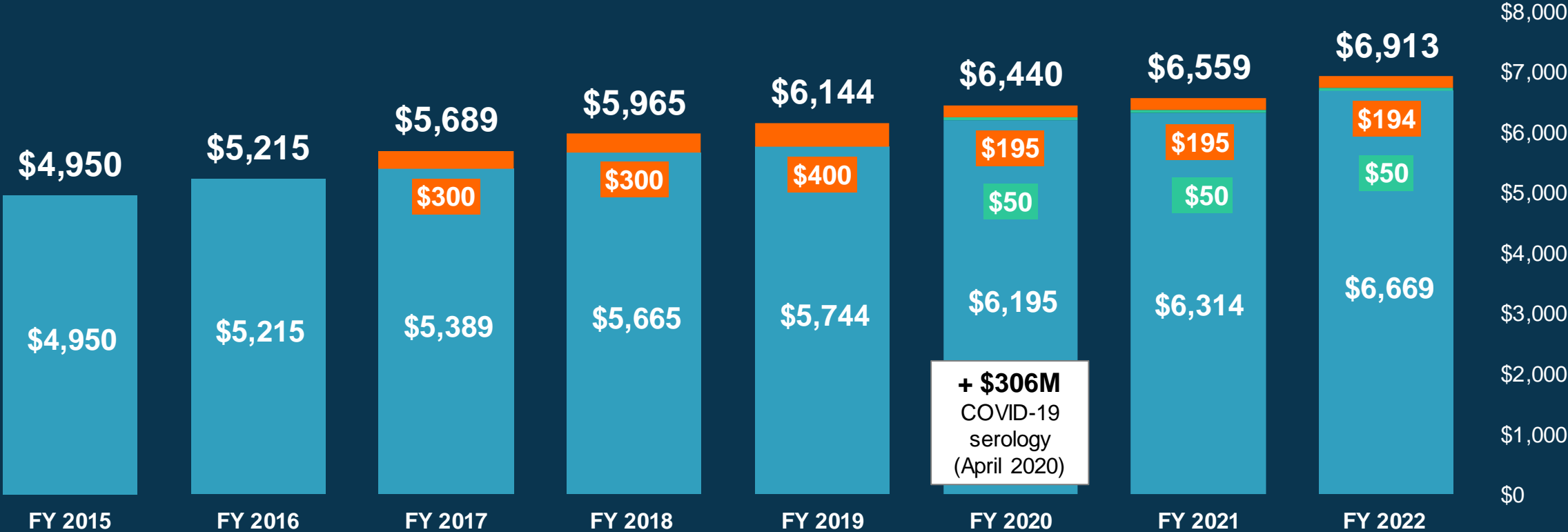
Ruben Mesa, MD – University of Texas San Antonio

Patty Spears – Patient Advocate, UNC Lineberger

George Wilding, MD – University of Wisconsin

NCI Appropriations FY 2015 – 2022 (in millions)

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



Also, ARPA-H: \$1B
(available FY 2022 - 24)

NCI Interim Paylines for FY 2022

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
Non-competing grants will be funded at 90% during this period of uncertainty.	

NCI is analyzing FY 22 results from Congress. Will set new paylines and non-competing funding soon.



NCI Bottom Line: A Blog about Grants and More

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Familiar Fiscal Challenges for NCI

December 6, 2021, by NCI Director Dr. Norman E. Sharpless

On the heels of Congress extending the Continuing Resolution for FY 2022, the NCI Director addresses what short-term funding means for NCI's grantee community. As in years past, Dr. Sharpless highlights the Institute's interim payline policies for both competing and noncompeting grants.

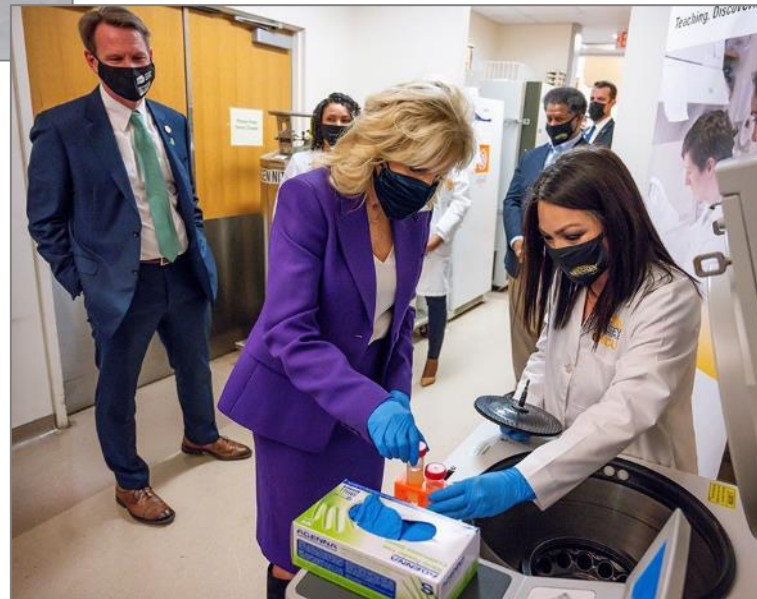
White House Commitment to New Cancer Moonshot Goals



“I’m proud to announce our plan to supercharge the Cancer Moonshot as a central effort of the Biden-Harris administration... This is a presidential priority. I will do my part on funding and using my authority as president to speed breakthroughs. I challenge and encourage all of you to do your part.”

— *President Joe Biden (February 2, 2022)*

First Lady Jill Biden and NCI Work Together on 'Returning to Screening'



President Biden Announces OSTP Leadership

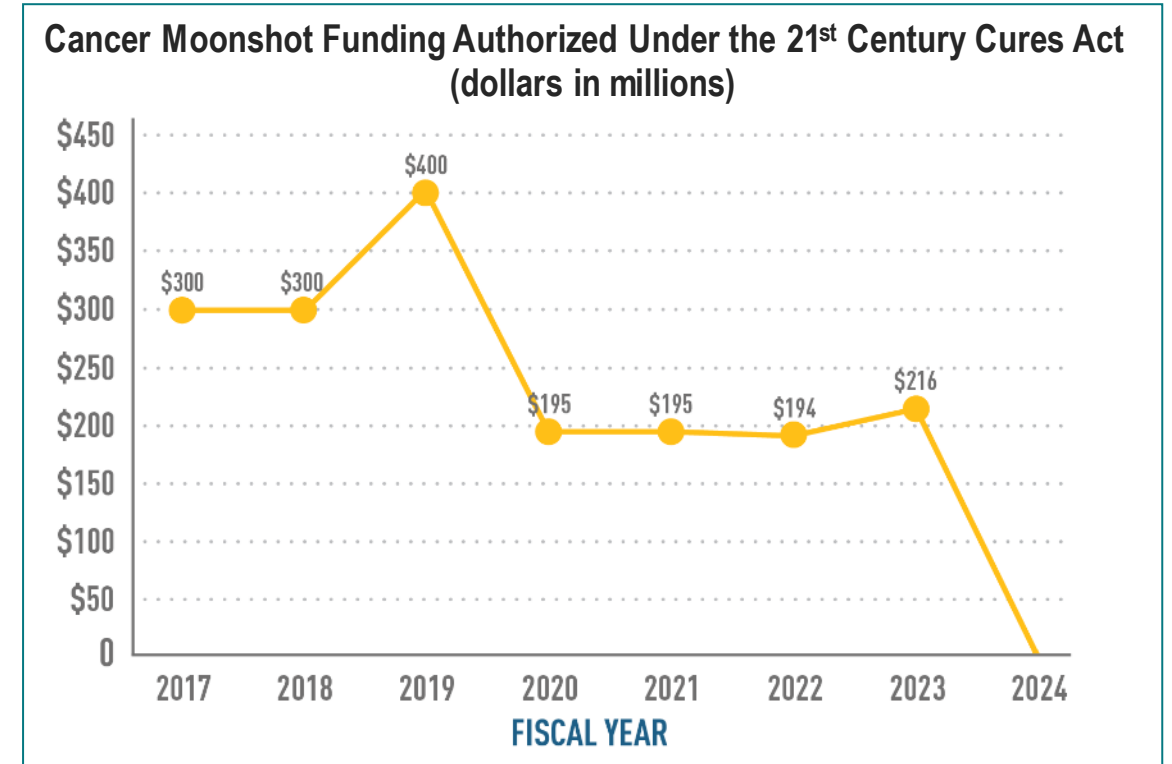


Dr. Alondra Nelson
Director of the White House Office
of Science and Technology Policy



Dr. Francis Collins
Science Advisor to the President and
Co-Chair of the President's Council of
Advisors on Science and Technology

Cancer MoonshotSM



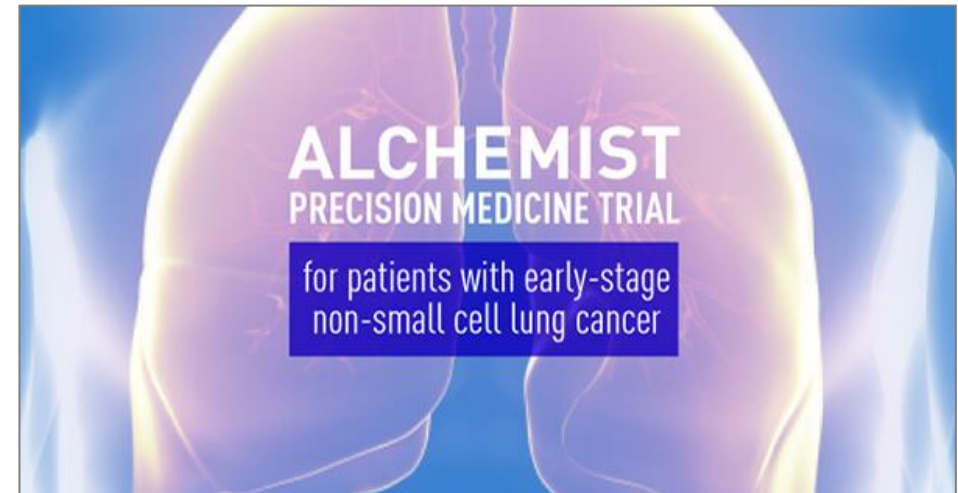
The Cancer Moonshot has three ambitious goals: to **accelerate scientific discovery in cancer**, **foster greater collaboration**, and **improve the sharing of data**.

ALCHEMIST – Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trials

Goal: To conduct one integrated program for screening target patient population to identify: EGFR mutations, ALK rearrangements, PD-L1 status

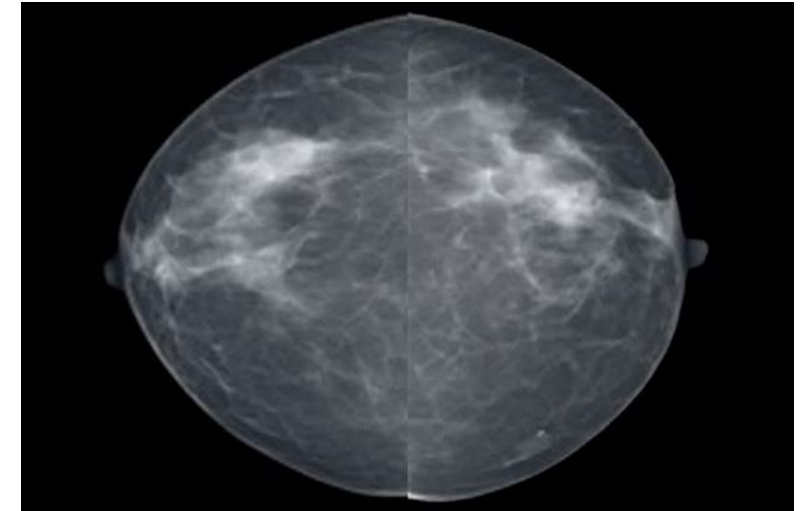
Current status:

- 6855 patients enrolled
- 6476 tissues processed to extract analytes
- 3656 cases fully characterized

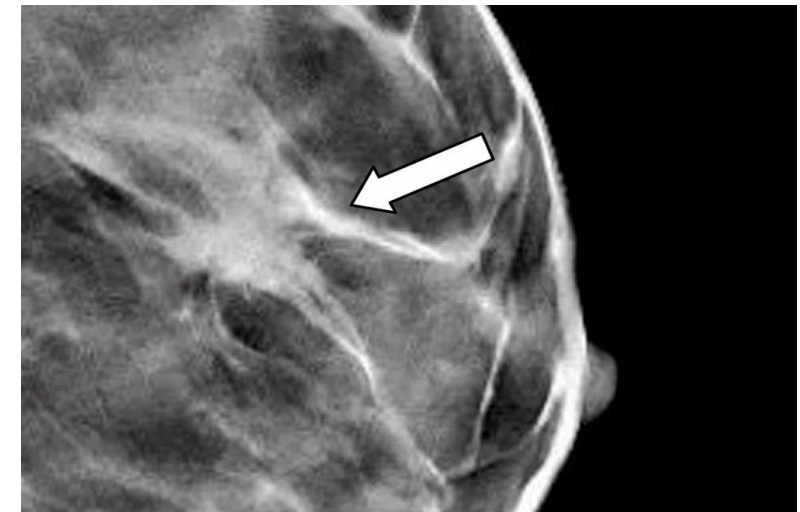


Tomosynthesis Mammographic Imaging Screening Trial (TMIST)

- Primary hypothesis: 3-D will decrease the cumulative incidence of advanced cancers, compared to standard 2-D digital mammography
- Academic-community partnership funded through the NCI Community Oncology Research Program (NCORP), conducted by ECOG/ACRIN Research Base
- **Accrual Goal: 65,508 / 128,905**

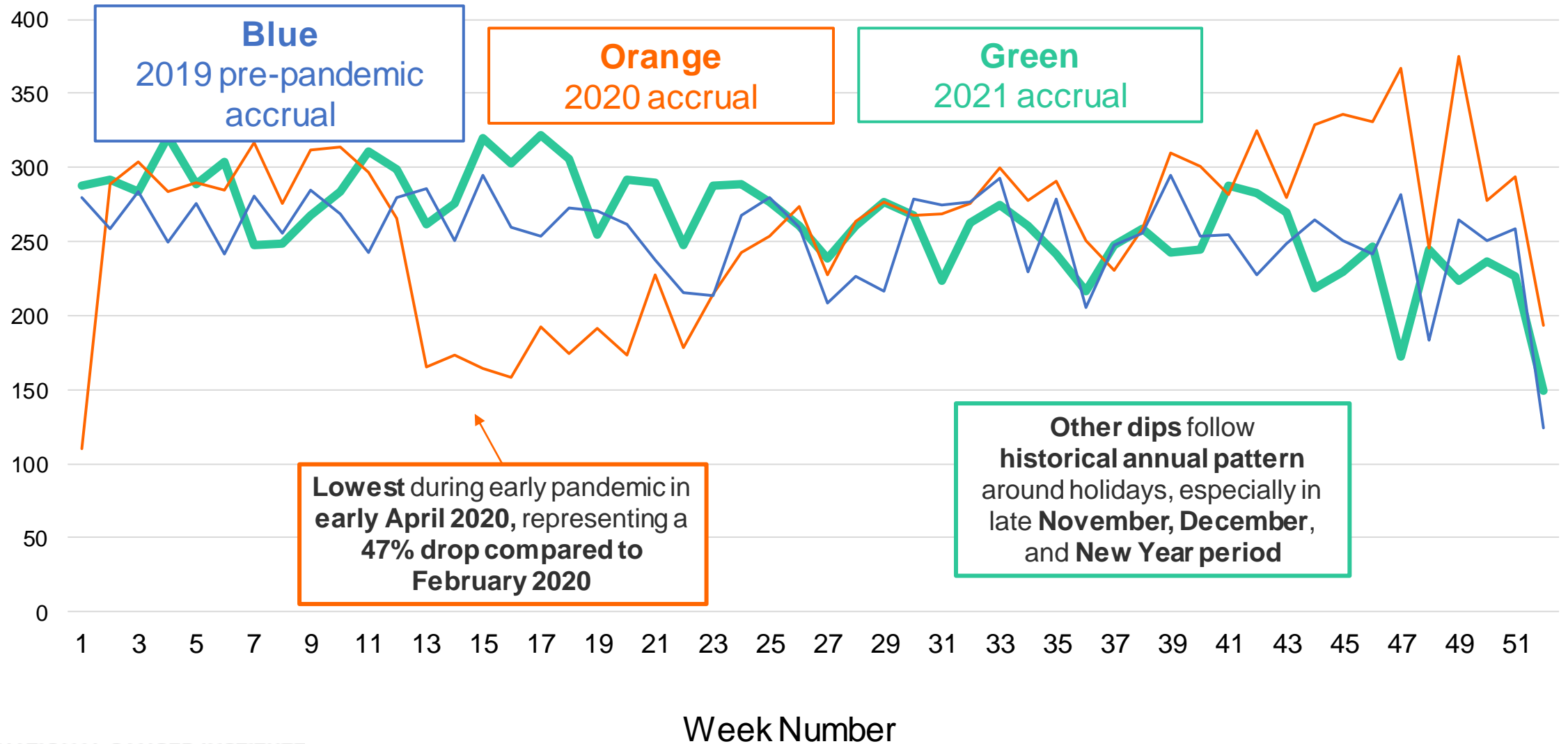


Routine 2-D digital mammogram



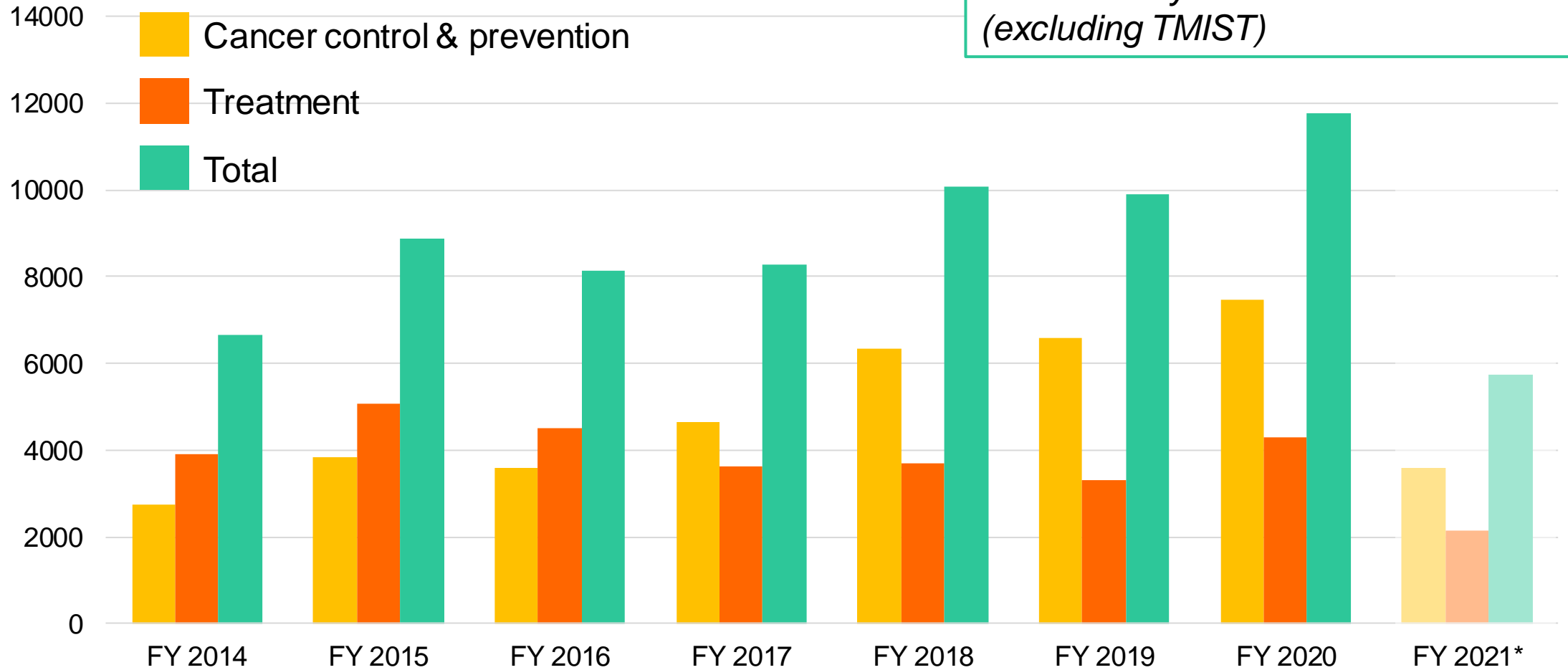
Magnified tomosynthesis view of the right breast

NCTN Weekly Accrual (2019, 2020, & 2021)



NCORP Accrual 2014 - 2022

Minority Accrual
 Community Sites: **23%**
 Minority/Underserved Sites: **50%**
Total minority accrual in 2021: 27%
(excluding TMIST)



**Partial data through February 2022*

Severe side effects of cancer treatment are more common in women than men

NIH NATIONAL CANCER INSTITUTE

Cancer Currents: An NCI Cancer Research Blog

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A blog featuring news and research updates from the National Cancer Institute.



Severe Side Effects of Cancer Treatment Are More Common in Women than Men

March 15, 2022, by NCI Staff

Women are more likely than men to experience severe side effects from cancer treatments such as chemotherapy, targeted therapy, and immunotherapy, a new study finds. Researchers hope the findings will increase awareness of the problem and help guide patient care.

[Continue Reading >](#)

cancer.gov/blog

- Published in *Journal of Clinical Oncology*, February 4, 2022
- Data from 202 SWOG trials involving more than **23,000 men and women**
- Overall, **women had a 34% higher risk** of severe side effects compared with men
- Sex disparity was **most pronounced for immunotherapy – women had a nearly 50% increased risk** of serious side effects compared with men

FORTE Five- or Ten-Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps

Primary Objective

Examine colorectal cancer incidence in participants with 1 to 2 non-advanced adenomas randomized to

- surveillance colonoscopy at 10 years

OR

- surveillance colonoscopy at 5 and 10 years.



- Sample size = 9,500 participants
- Trial: NCT05080673
- Study started in October 2021
- Currently recruiting

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.

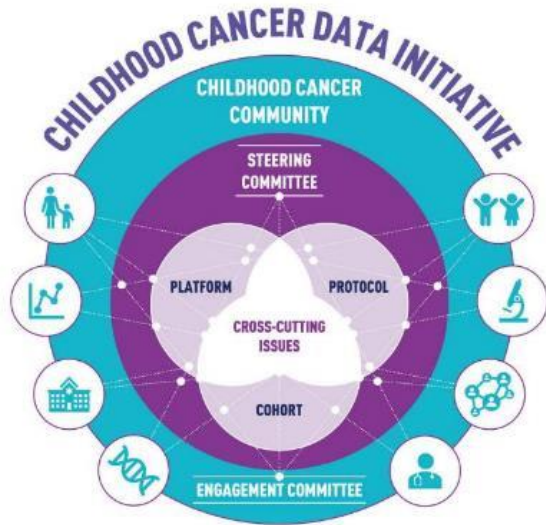
FUNDING OPPORTUNITY:

Data, Evaluation and Coordinating Center for CUSP2CT (U24)

FOA No. RFA-CA-22-014

Submissions due: **March 28, 2022**

Childhood Cancer Data Initiative



CCDI Annual Symposium

Video available at
cancer.gov/ccdi

Childhood Molecular Characterization Initiative

- Open to all children with cancer
- Will provide clinical and molecular information to every child with cancer
- Builds on *Project: EveryChild*
- Will characterize ~3,000 children with hard-to-treat cancers

National Childhood Cancer Registry

- Integrates data from registries, hospitals, research centers, insurers
- Will generate accurate count of cancer cases
- Database to expand with genomic and tumor characteristics, treatment info, recurrence indicators, etc.

NCI Personnel Announcement



Dr. Brigitte Widemann

**Special Advisor to the Director
for Childhood Cancer**

Discussion