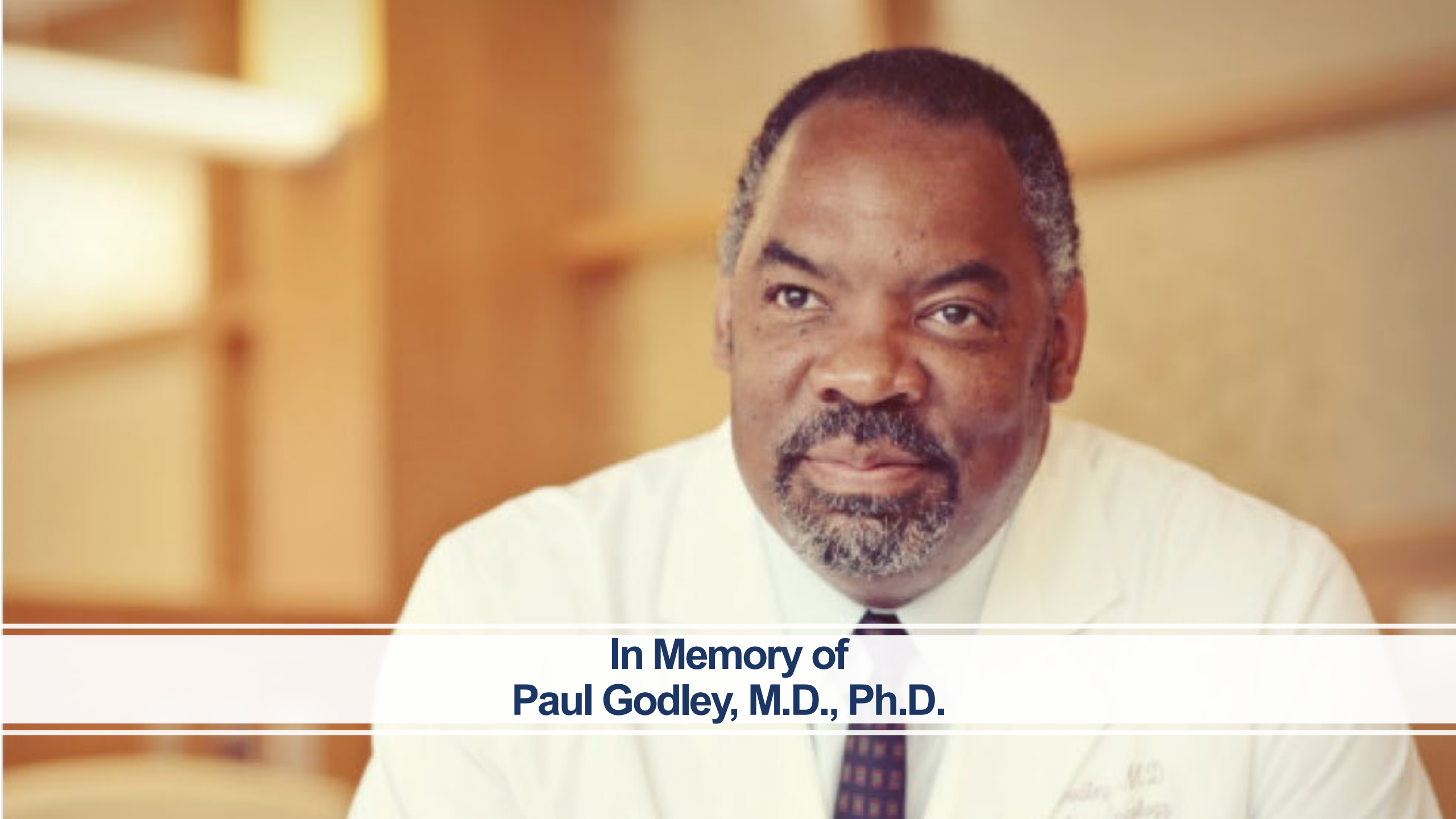


NCI Director's Update

*Clinical Trials and Translational Research
Advisory Committee - July 17, 2019*

Douglas R. Lowy, M.D.
Acting Director

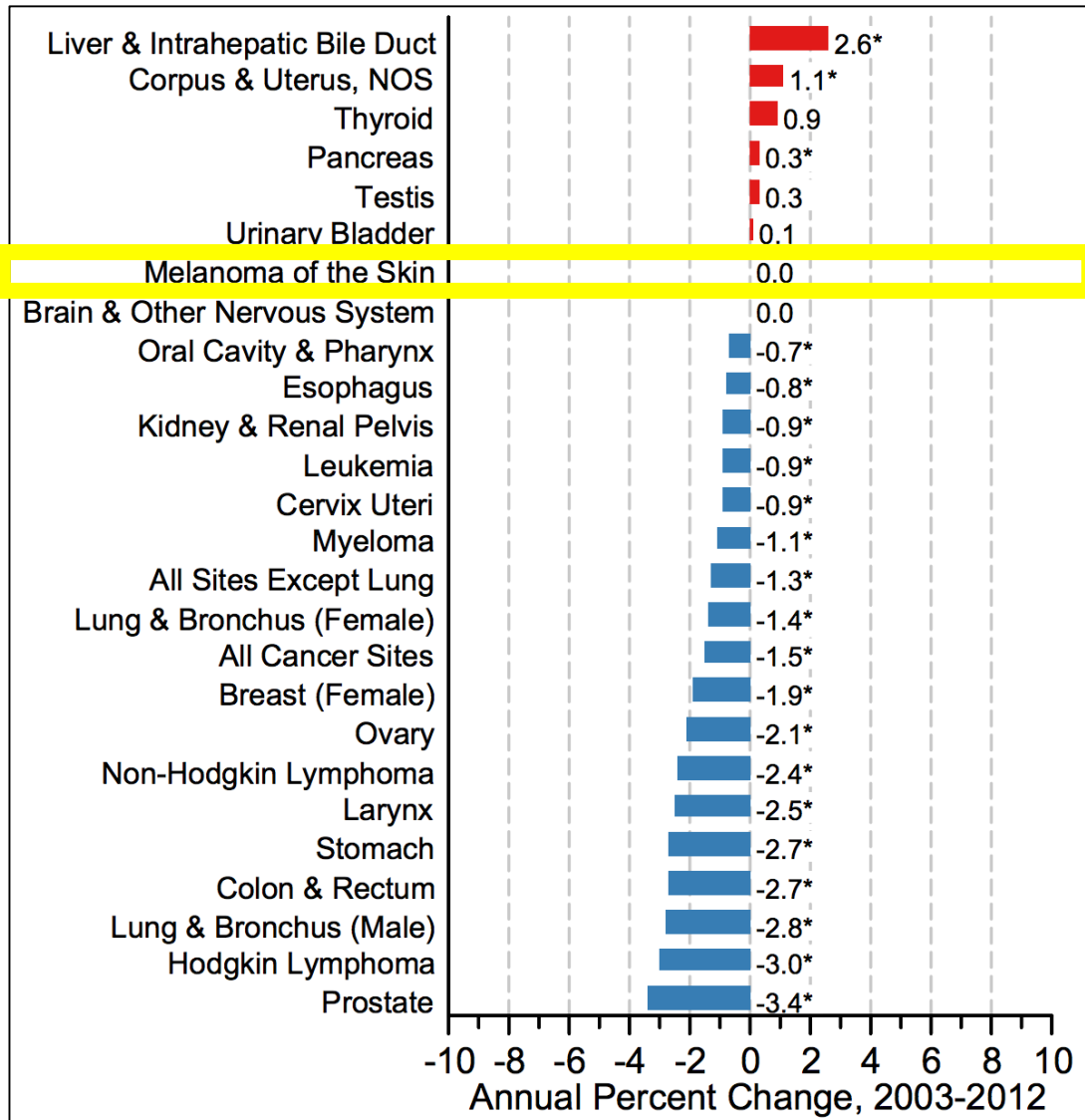
@TheNCI
@NCIDrDougLowy



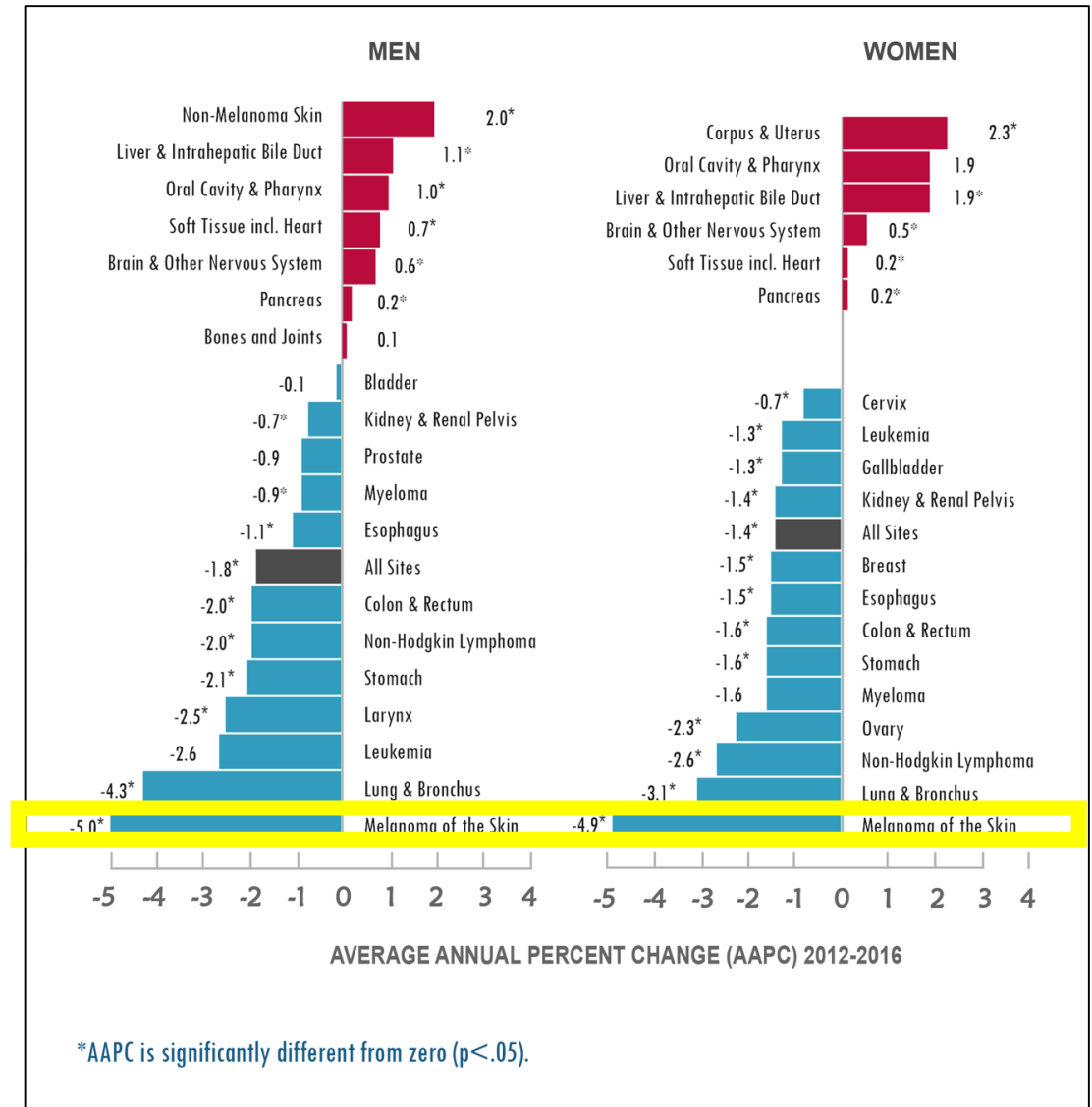
**In Memory of
Paul Godley, M.D., Ph.D.**

National Trends in Cancer Death Rates: Annual Percent Change

Annual Report to the Nation, 2015*



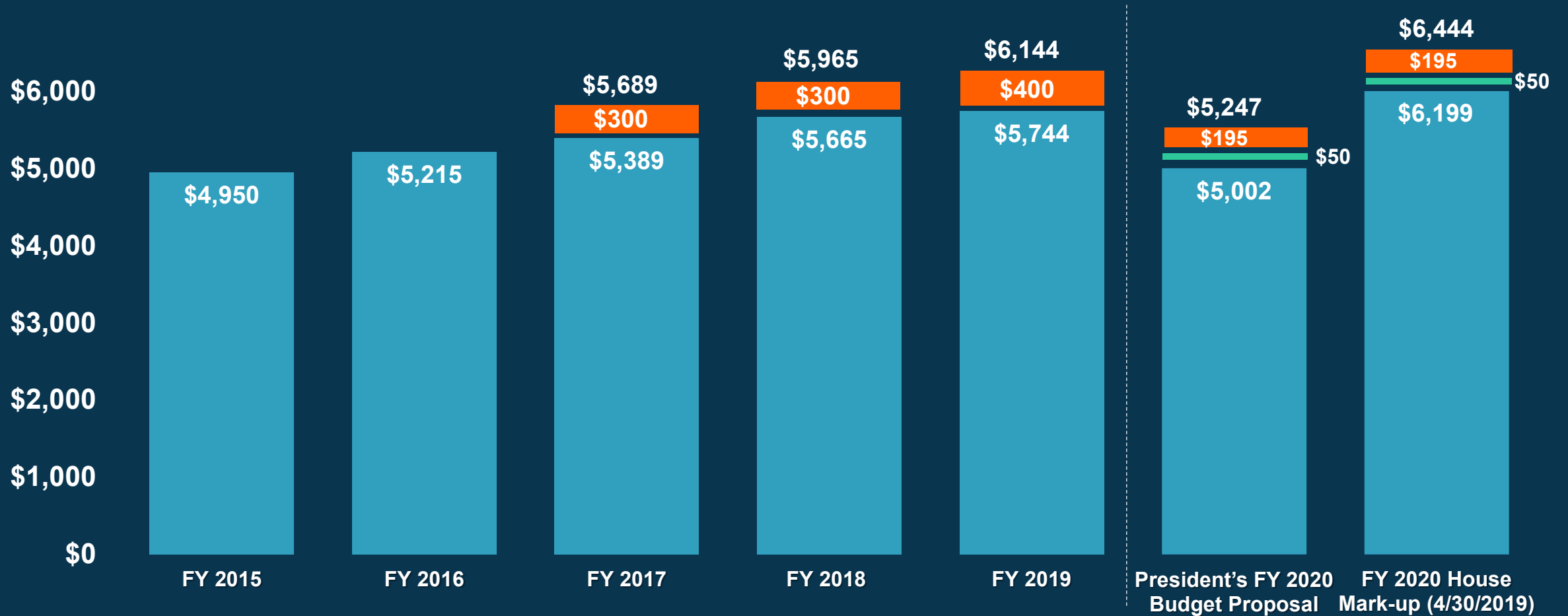
Annual Report to the Nation, 2019



*AAPC is significantly different from zero (p<.05).

NCI Appropriations FY 2015 – 2020 (in millions)

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





NCI/NIH BUDGET PROCESS FOR REGULAR APPROPRIATION

STEP 1



White House OMB coordinates with federal agencies to formulate the President's budget proposal

STEP 2



Congressional appropriations committees consider President's proposal & prepare legislation

STEP 3



Congress reconciles & finalizes appropriations legislation & sends to the President

STEP 4



President signs the appropriations bill into law making funds available for NIH & NCI

FY 2020

FY 2019

Select Working Group Updates

Small Cell Lung Cancer (SCLC)

Co-Chairs:

Alex Adjei, M.D., Ph.D.

Laurie Gaspar, M.D.,
M.B.A., F.A.S.T.R.O.

Glioblastoma (GBM)

Co-Chairs:

Walter J. Curran, Jr.
M.D., F.A.C.R.

Chi V. Dang, M.D., Ph.D.

Four Areas of Added Emphasis



**CHILDHOOD
CANCERS**



**INVESTIGATOR-
INITIATED
RESEARCH**

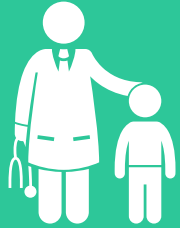


**HEALTH
DISPARITIES**



**DRUG
RESISTANCE**

Four Areas of Added Emphasis



**CHILDHOOD
CANCERS**



**INVESTIGATOR-
INITIATED
RESEARCH**



**HEALTH
DISPARITIES**



**DRUG
RESISTANCE**

Updates on NCI-COG Pediatric MATCH

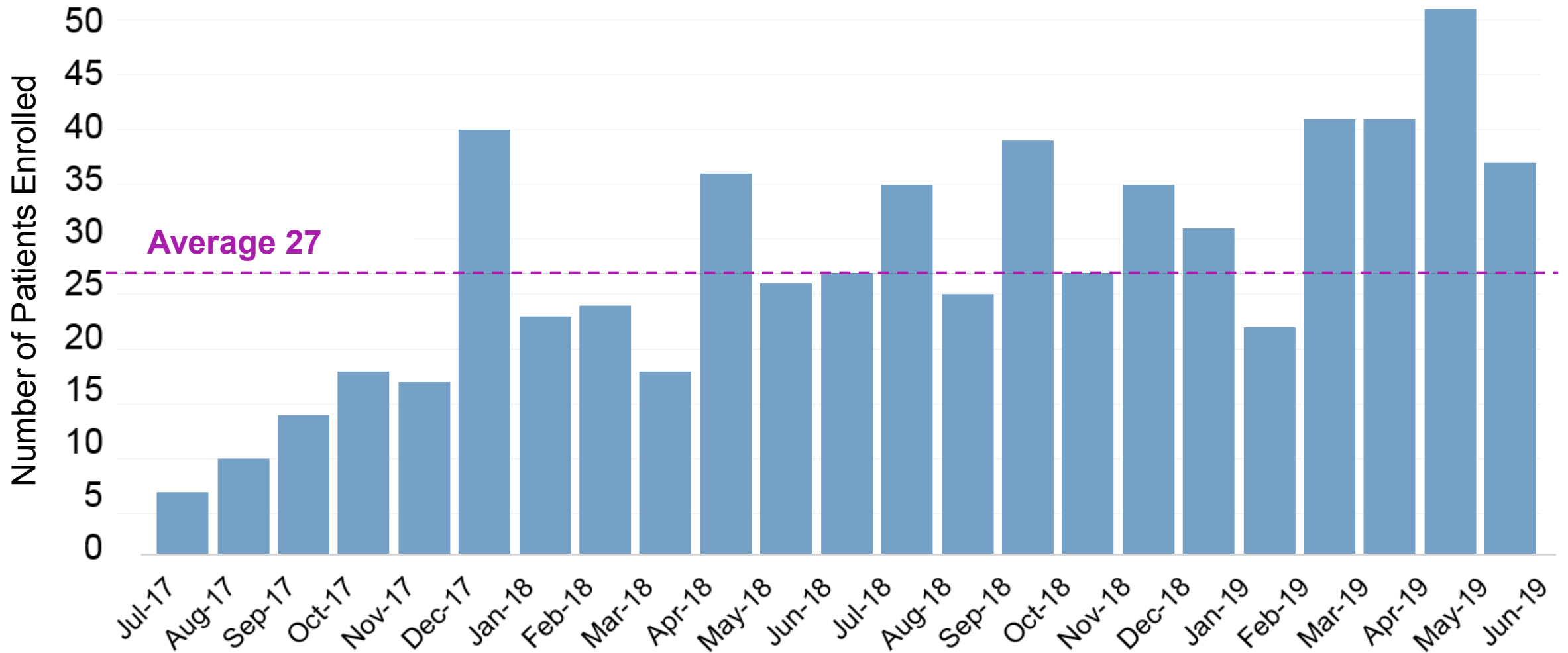
Study activated July 2017

- As of July 2019:
 - 645 patients enrolled
 - Monthly accrual average: 27
 - 10 treatment arms, with at least one patient enrolled on each one
 - Approximately 25% of study patients with tumor submitted have been assigned to a treatment arm
 - 10% enrolled on treatment to date

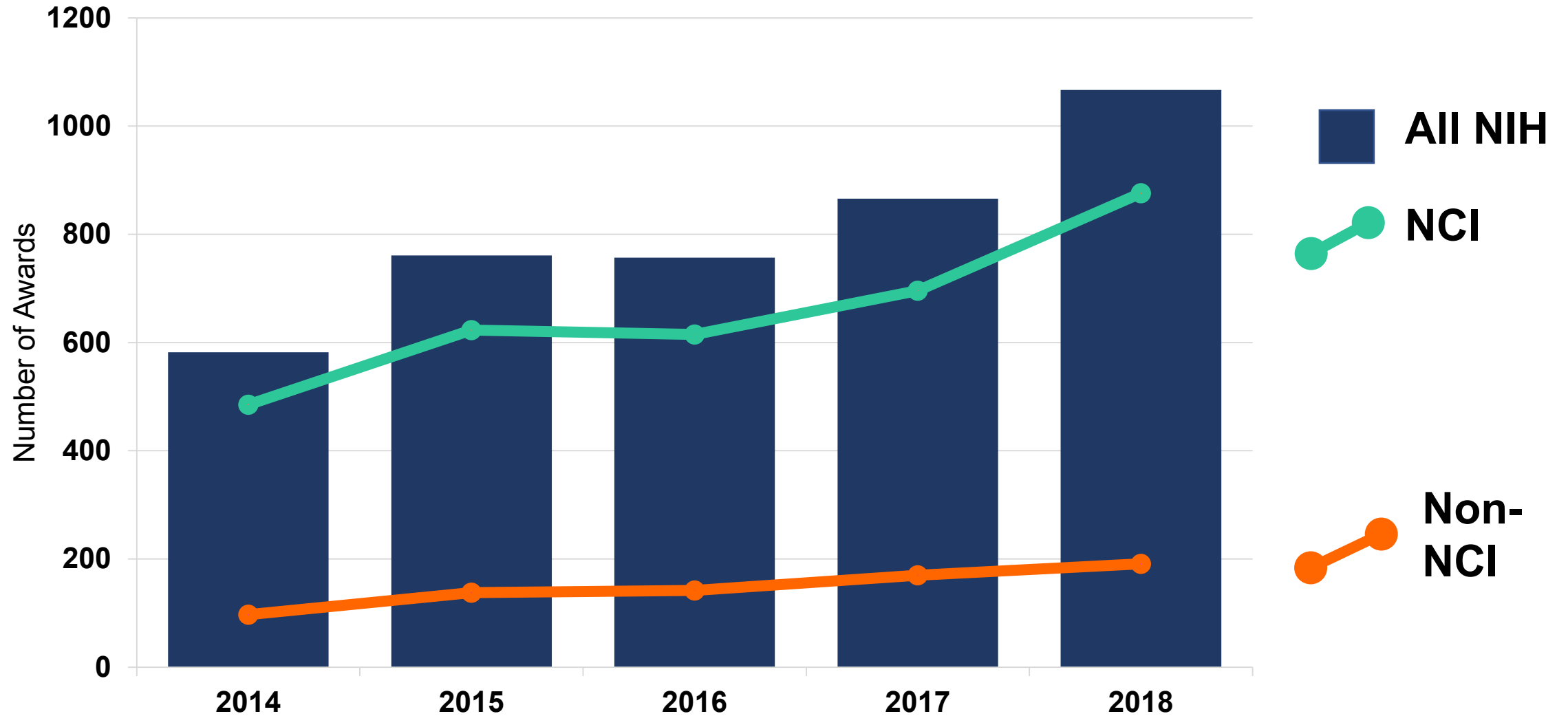
NCI-COG Pediatric MATCH has created a collaborative framework for efficient collection, processing, and sequencing of refractory pediatric cancers.



NCI-COG Pediatric MATCH Accrual



Pediatric cancer research conducted or supported by NCI/NIH: 2014 - 2018

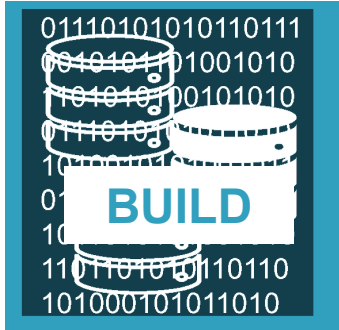


Childhood Cancer Research Presidential Initiative

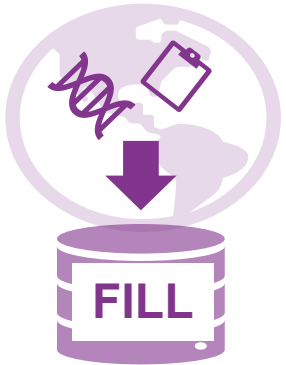


- President's FY 2020 budget proposal includes \$50M
- White House has convened several stakeholder events

Childhood Cancer Data Initiative (CCDI)



Facilitate the sharing of childhood cancer data from multiple sources through a connected data infrastructure



Identify opportunities to align and integrate multiple data sources to make data work better for patients, clinicians, and researchers



Maximize every opportunity to improve treatments and outcomes for children with cancer

Childhood Cancer Data Initiative – Next Steps

Scientific Planning Meeting

July 29-31, 2019

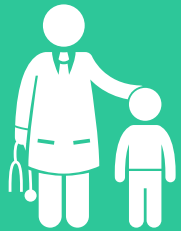
Washington, D.C.

For more information and to register for the videocast, visit

[Cancer.gov](https://www.cancer.gov) > search > **CCDI**



Four Areas of Added Emphasis



**CHILDHOOD
CANCERS**



**INVESTIGATOR-
INITIATED
RESEARCH**

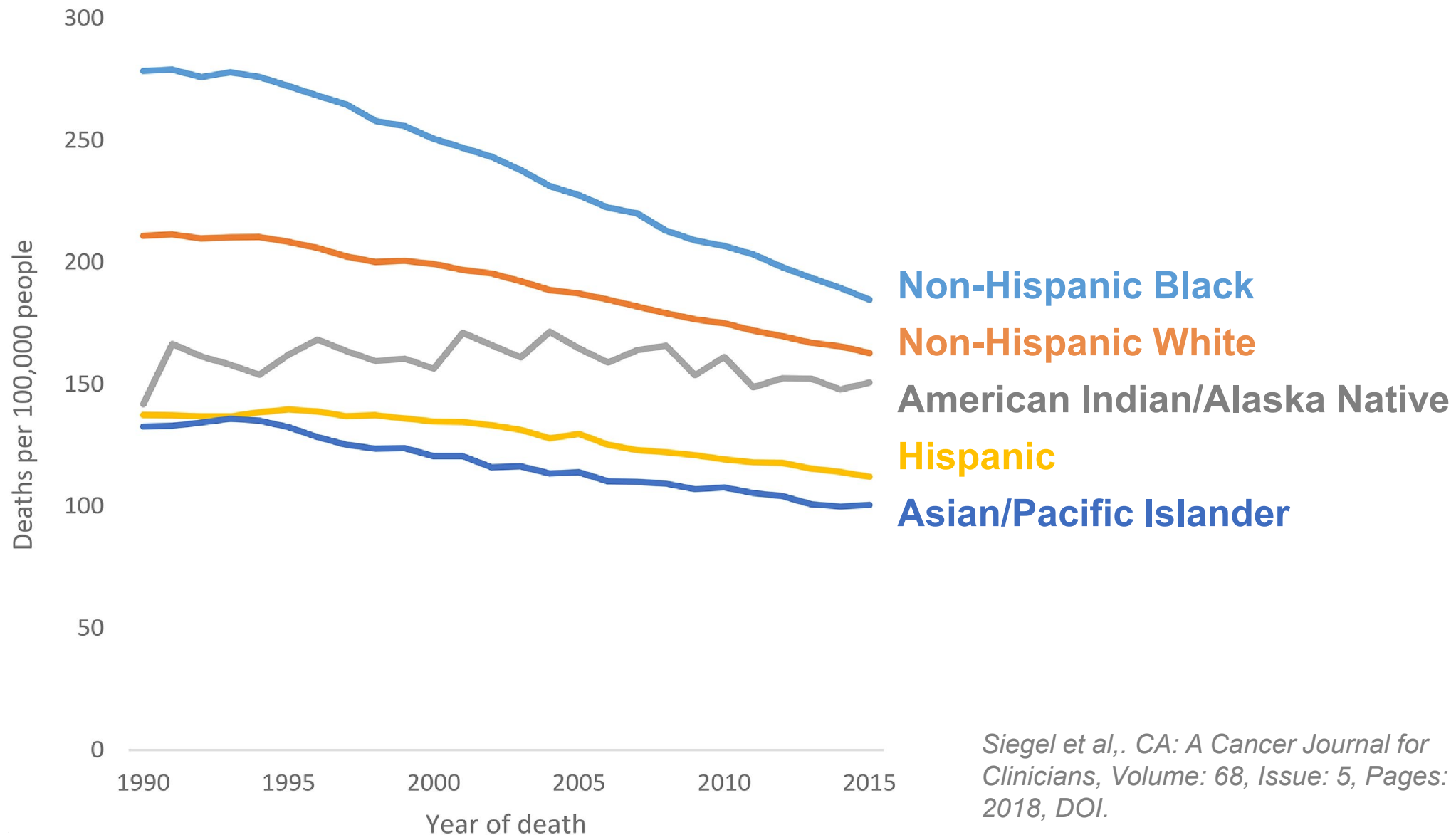


**HEALTH
DISPARITIES**



**DRUG
RESISTANCE**

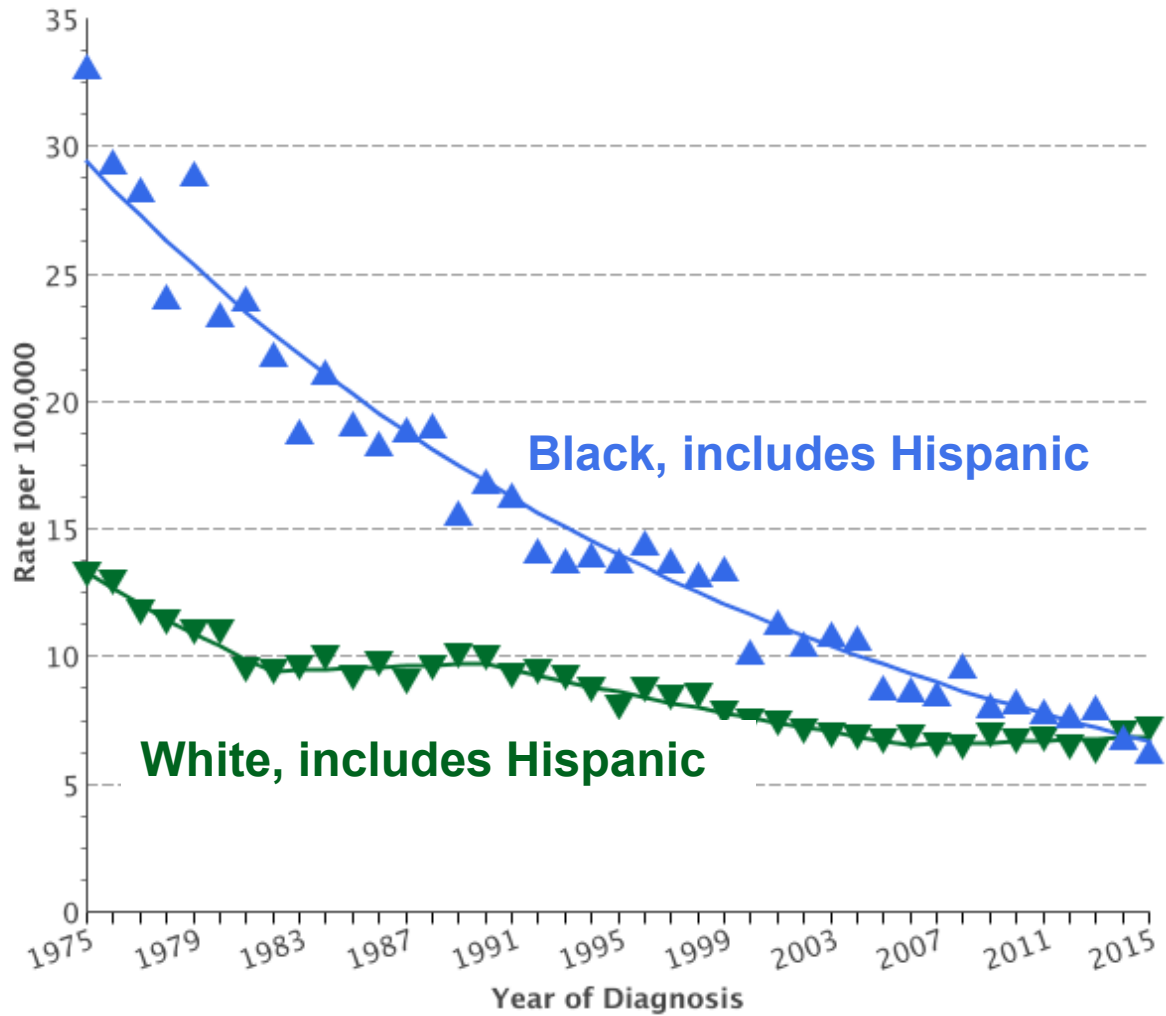
U.S. cancer mortality trends by race/ethnicity: 1990-2015



Siegel et al., *CA: A Cancer Journal for Clinicians*, Volume: 68, Issue: 5, Pages: 329-339, 2018, DOI.

Cervical cancer incidence in the U. S.

- **Incidence in black women is now similar to white women.**
- **Mortality disparity remains.**

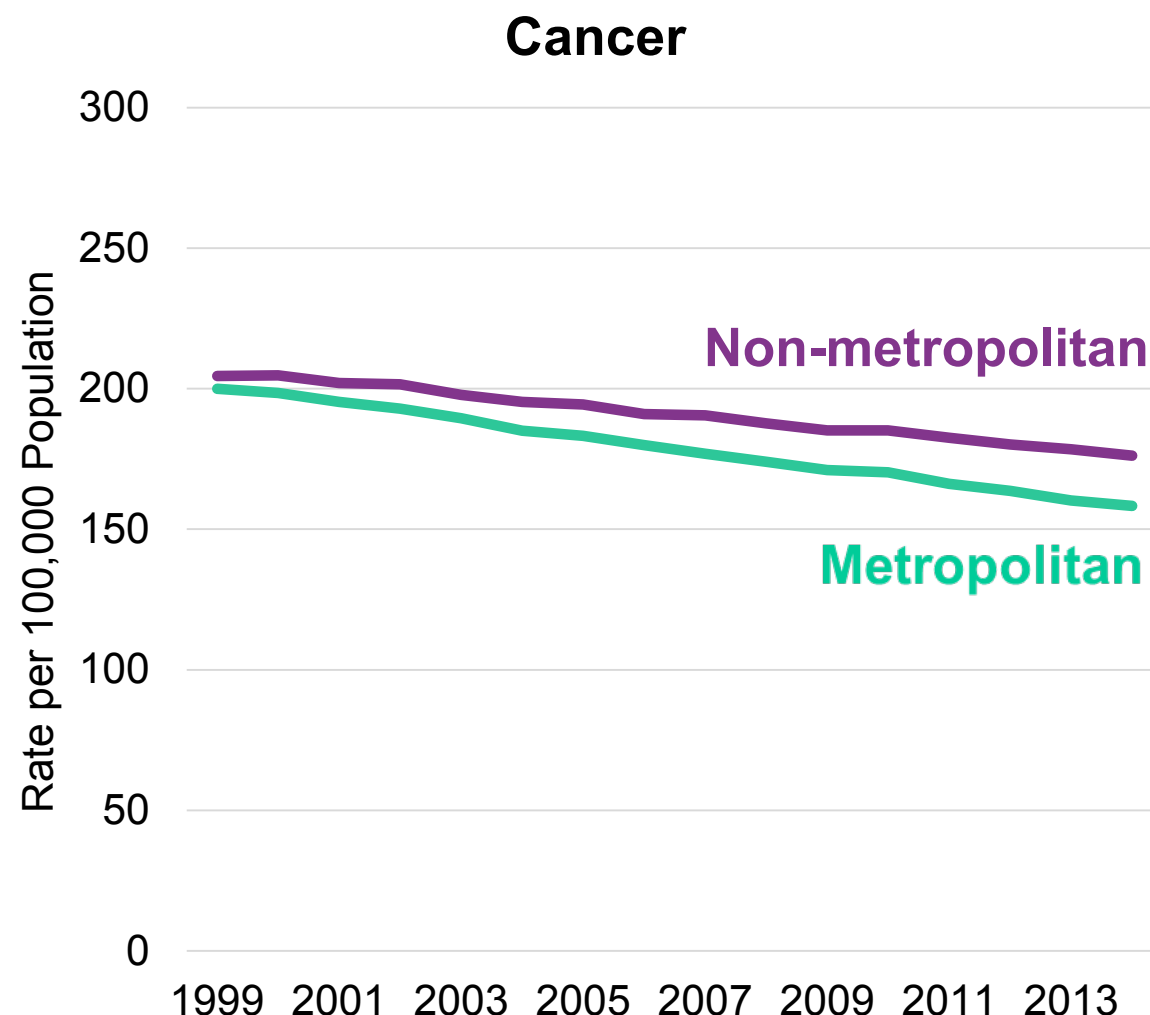
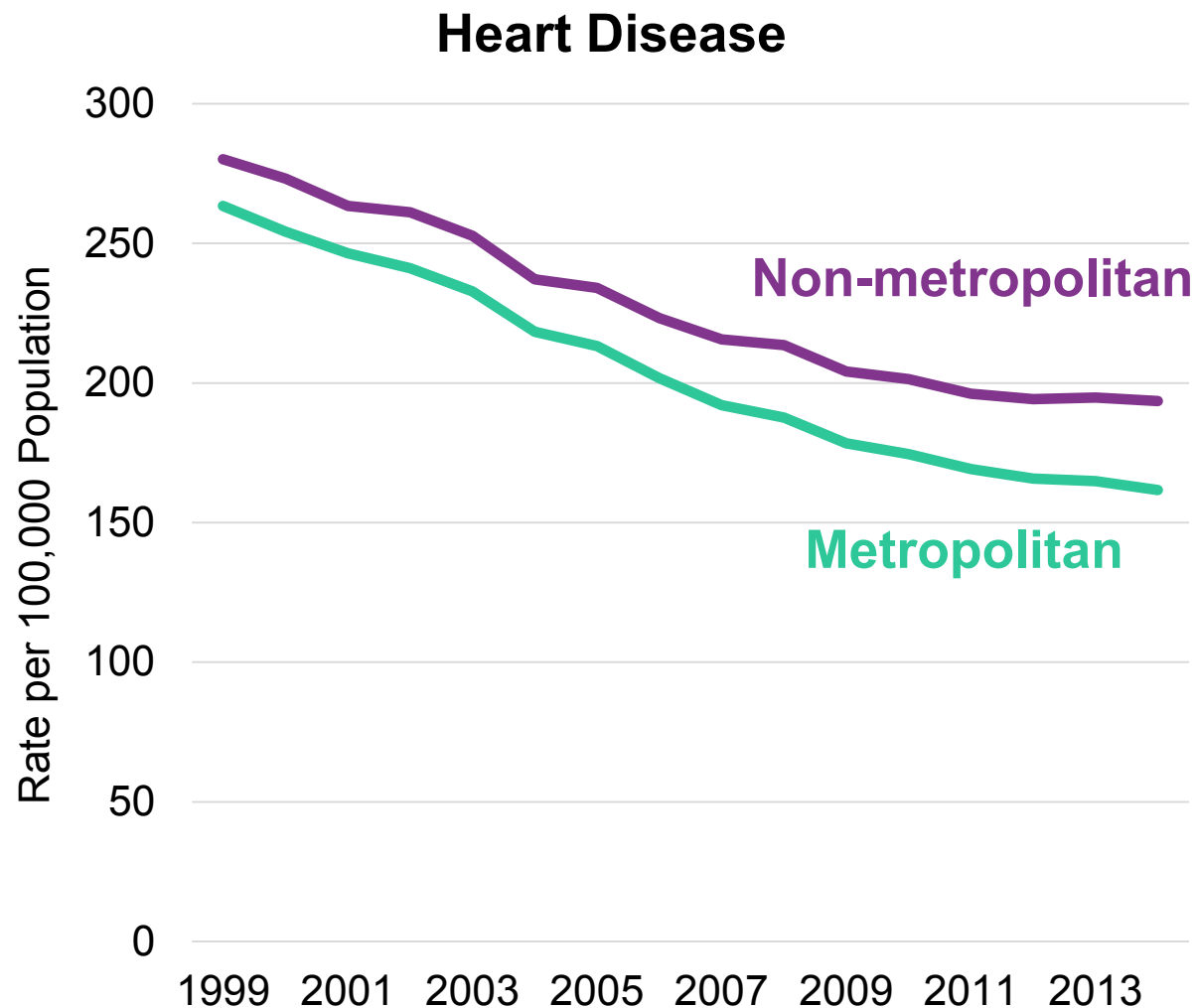


**Current mortality rates
ASR* 2012-2016**

Black women: 3.5
White women: 2.2

**ASR=Annual Standardized Rate*

Heart disease and cancer mortality rates, age adjusted



NCI Activities in Rural Cancer Control

- 21 Cancer Centers received supplements in FY18 to focus on rural populations.
- RFA-CA-18-026 (R01) *Improving the Reach and Quality of Cancer Care in Rural Populations* (Closed)

Additional relevant FOAs

Collaborative Minority Health and Health Disparities Research with Tribal Epidemiology Centers	R21 PAR-17-483 R01 PAR-17-484	12/5/2019
Research to Improve Native American Health	R01 PAR-17-496 R21 PAR-17-464	5/14/2020
Administrative Supplements to Support Cancer Disparity Collaborative Research	P30 PA-18-842	9/10/2019, 9/10/2020

Four Areas of Added Emphasis



**CHILDHOOD
CANCERS**



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RESEARCH**

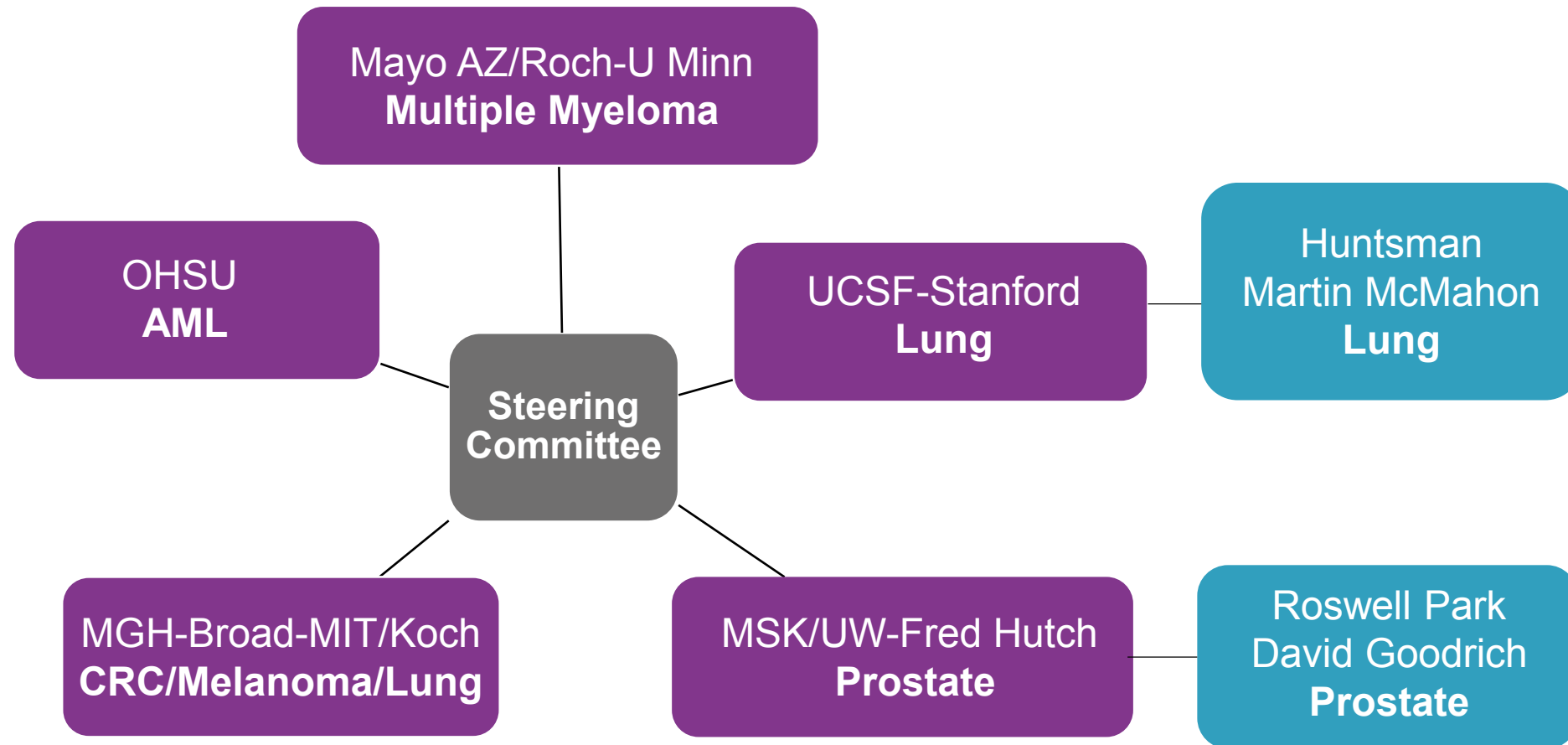


**HEALTH
DISPARITIES**



**DRUG
RESISTANCE**

NCI Drug Resistance & Sensitivity Network



NCI Drug Resistance & Sensitivity Network



Collaboration with other NCI & Cancer Moonshot Programs

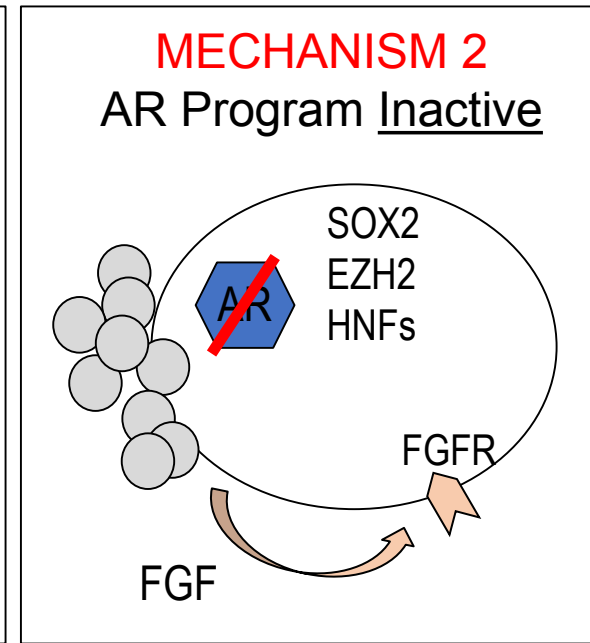
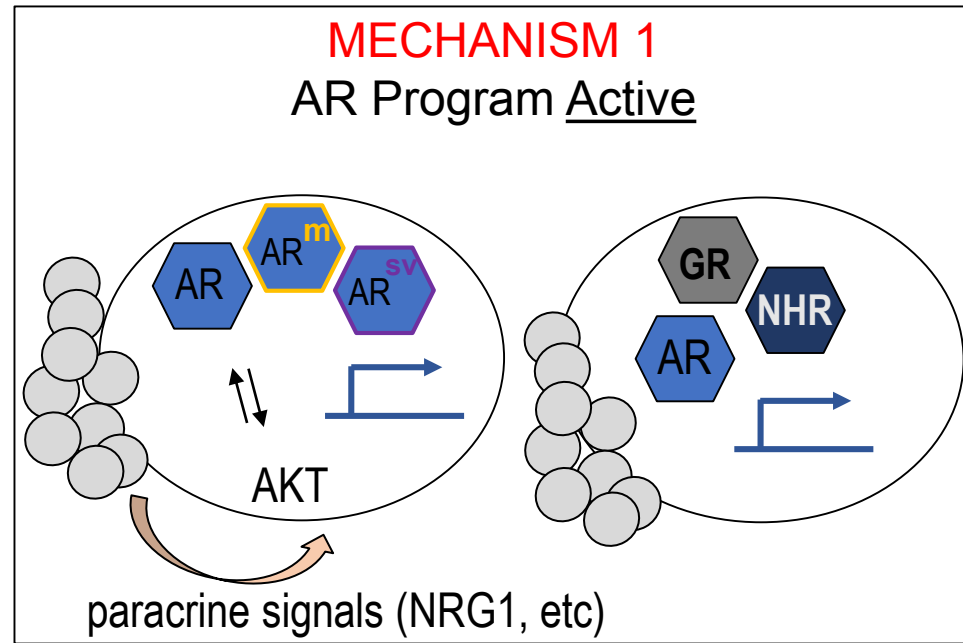
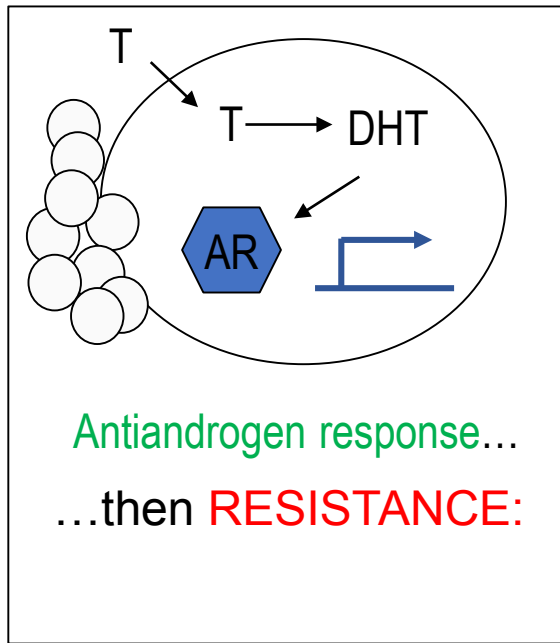
- **ETCTN** - Experimental Therapeutics Clinical Trials Network
- **PDXNet/PDMR** - PDX Dev & Trial Ctrs Res Network/Patient-Der Models Rep
- **CHTN** – Cooperative Human Tissue Network
- **PADIS** – Pharmacodynamic Assay Development & Implementation Section
- **Moonshot Biobank**
- **HTAN/MCL** - Human Tumor Atlas Network & Mol & Cell Characterization of Screen-Detected Lesions Consortium
- **IOTN** – Immuno-Oncology Translational Network
- **CSBC** – Cancer Systems Biology Consortium

Administrative Supplement Goal:

to promote collaborations between DRSN & non-DRSN investigators.

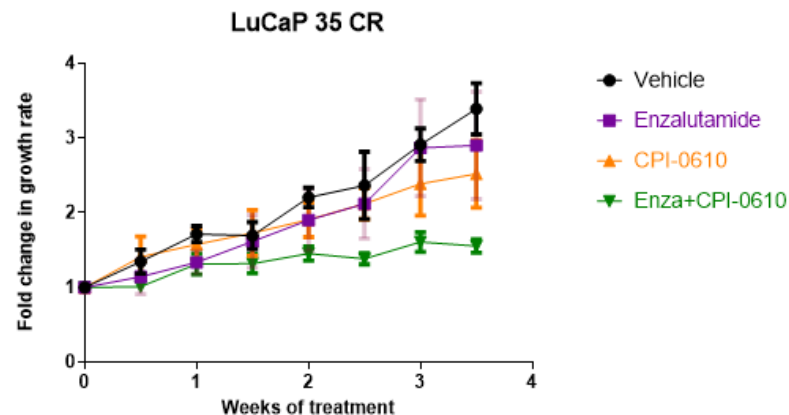
NCI Drug Resistance & Sensitivity Network

MSK/UW-Fred Hutch Prostate Cancer DRSC

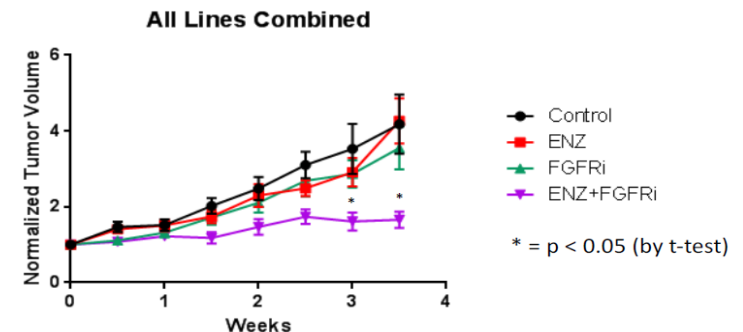


Activity of Clinical Grade Inhibitors in PDX Models of Castration Resistant Prostate Cancer in combination with enzalutamide

ARi + BETi: Combination



ARi + FGFRi: Combination



Next Steps

Present Status

- Preference given to DRSN studies involving NCI CTEP IND agents
- NCI-IND agents (n= >60) include a wide variety of small molecule and antibody inhibitors that impact classic oncogenic signaling & checkpoint targets

Future Directions

- Encourage collaborations with associate/non-DRSN members
- Promote the interface of Trans-NCI Moonshot Networks
 - PaCMEN
 - HTAN
 - PDXNet
 - IOTN
 - PI-DDN
 - CIMACs/CIDC
 - FusOnC2

Recent Leadership Appointments

- Deputy Director for Scientific Strategy and Development - **Dinah Singer**
- Chief of Staff - **Anne Lubenow**
- Deputy Executive Officer - **Eric Cole**
- Director, CBIIT - **Tony Kerlavage**
- Chief Information Officer - **Jeff Shilling**
- Chief Data Scientist, DCEG - **Jonas Almeida**
- Budget Director - **Weston Ricks**

Leadership Vacancies

Director, Center for Global Health (CGH)

Bob Croyle, Acting

Associate Director, Cancer Therapy Evaluation Program (CTEP)

Meg Mooney, Acting

Director, Division of Cancer Prevention (DCP)

Debbie Winn, Acting



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INSTITUTE**

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