

NCI Director's Report

Norman E. Sharpless, M.D.

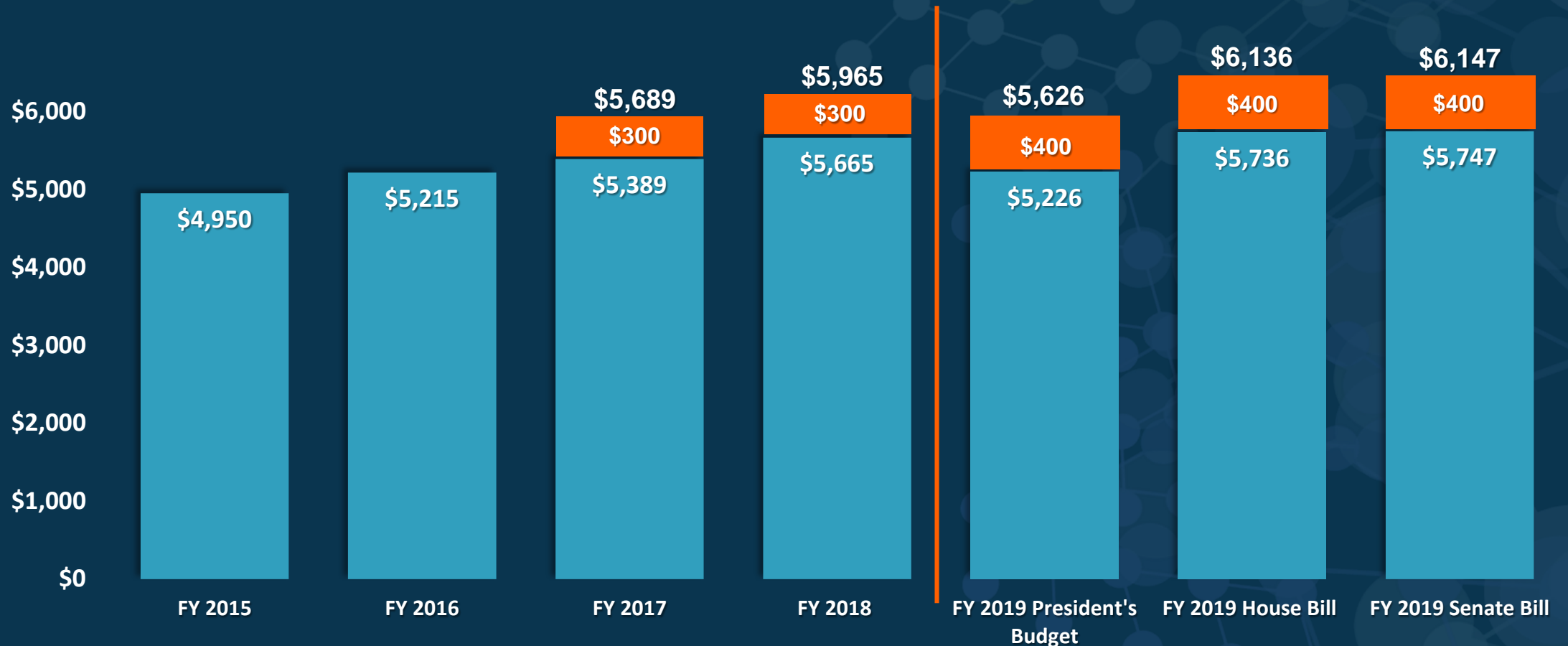
August 14, 2018

Updates

- Budget
- Legislative Update
- Cancer Moonshot
- Workforce Development: R50 Award
- Rare Tumor Patient Engagement Network
- RESPOND

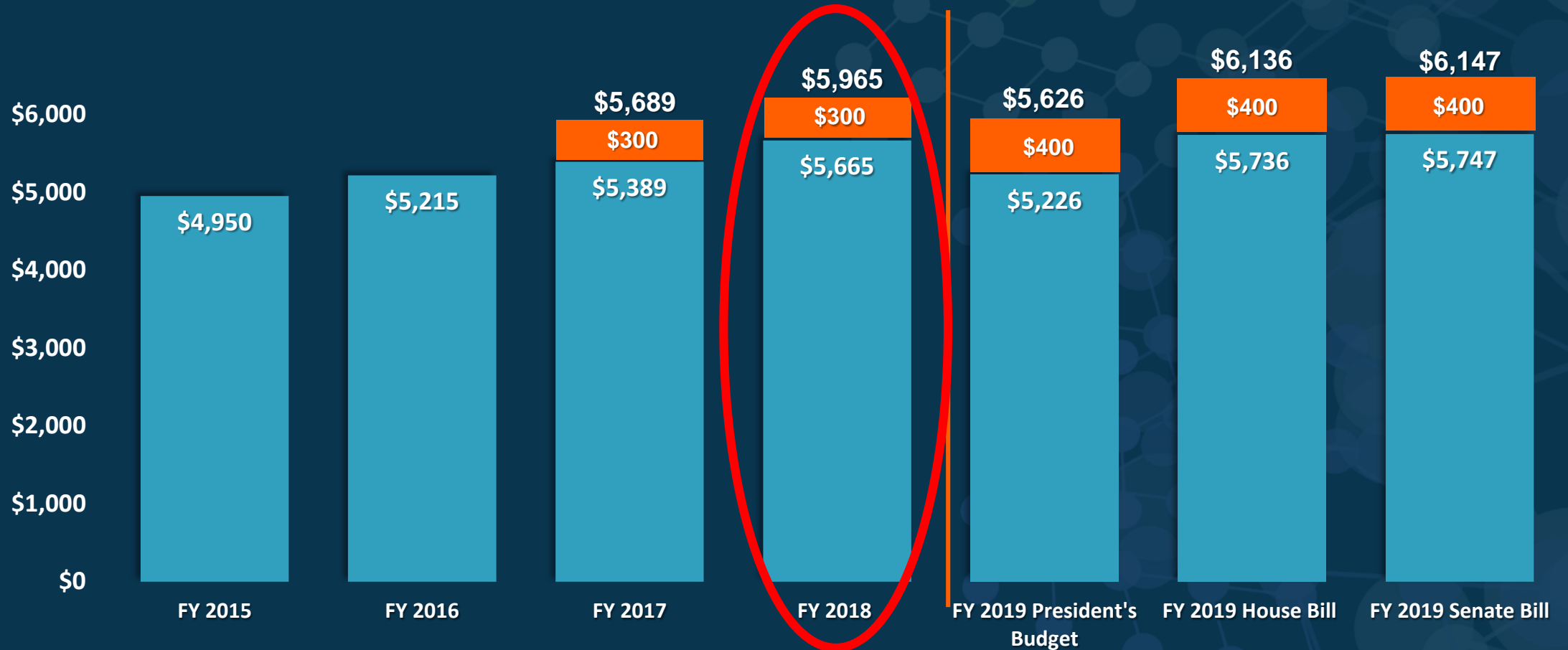
Budget

NCI Appropriations FY 2015-2019 (in millions)



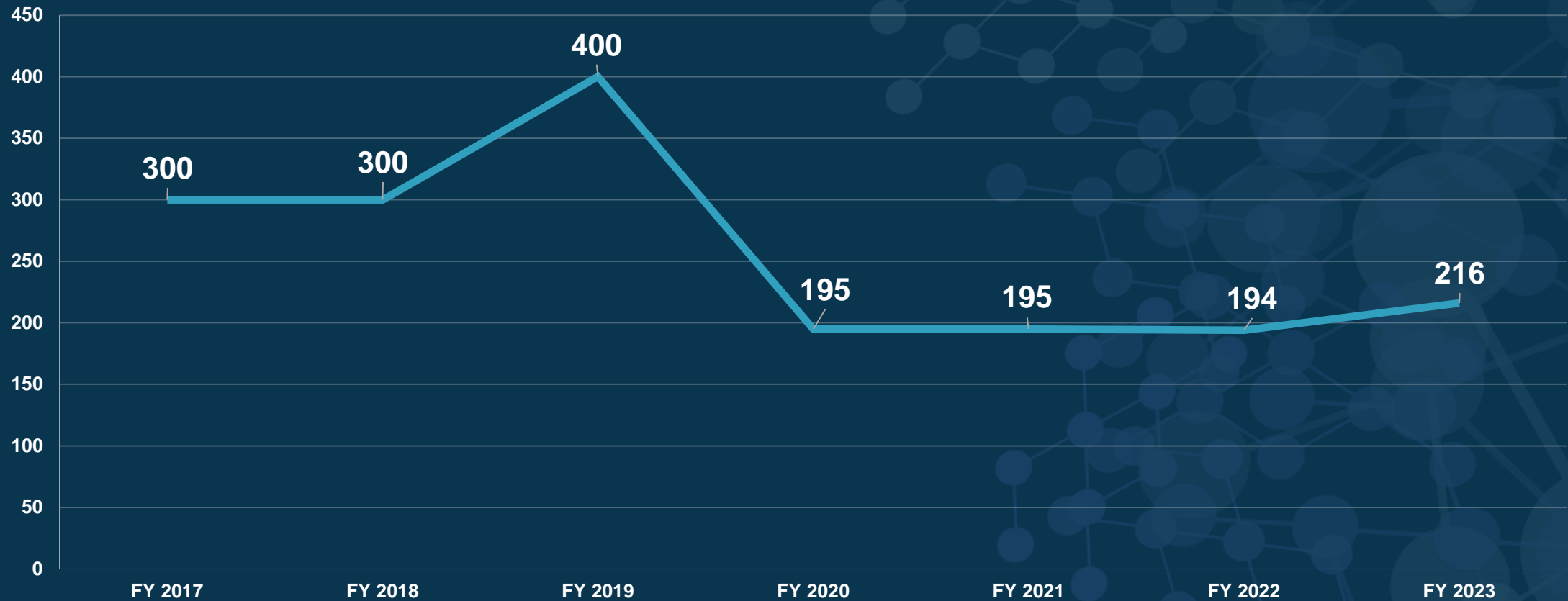
Source: NCI Office of Budget and Finance

NCI Appropriations FY 2015-2019 (in millions)



Source: NCI Office of Budget and Finance

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



Legislative Update

FY 2019 – Appropriators Have Proposed Increases for NIH and NCI (4th year in a row)

House Appropriations Committee (passed 7/11)

- \$1.25 billion increase for NIH
- \$71 million increase for NCI base budget
- \$400 million for Cancer Moonshot

Senate Appropriations Committee (passed 6/28)

- \$2 billion increase for NIH
- \$82 million increase for NCI base budget
- \$400 million for Cancer Moonshot



Rep. Rosa DeLauro (D-CT)
Ranking Member



Rep. Tom Cole (R-OK)
Chair



Sen. Patty Murray (D-WA)
Ranking Member



Sen. Roy Blunt (R-MO)
Chair



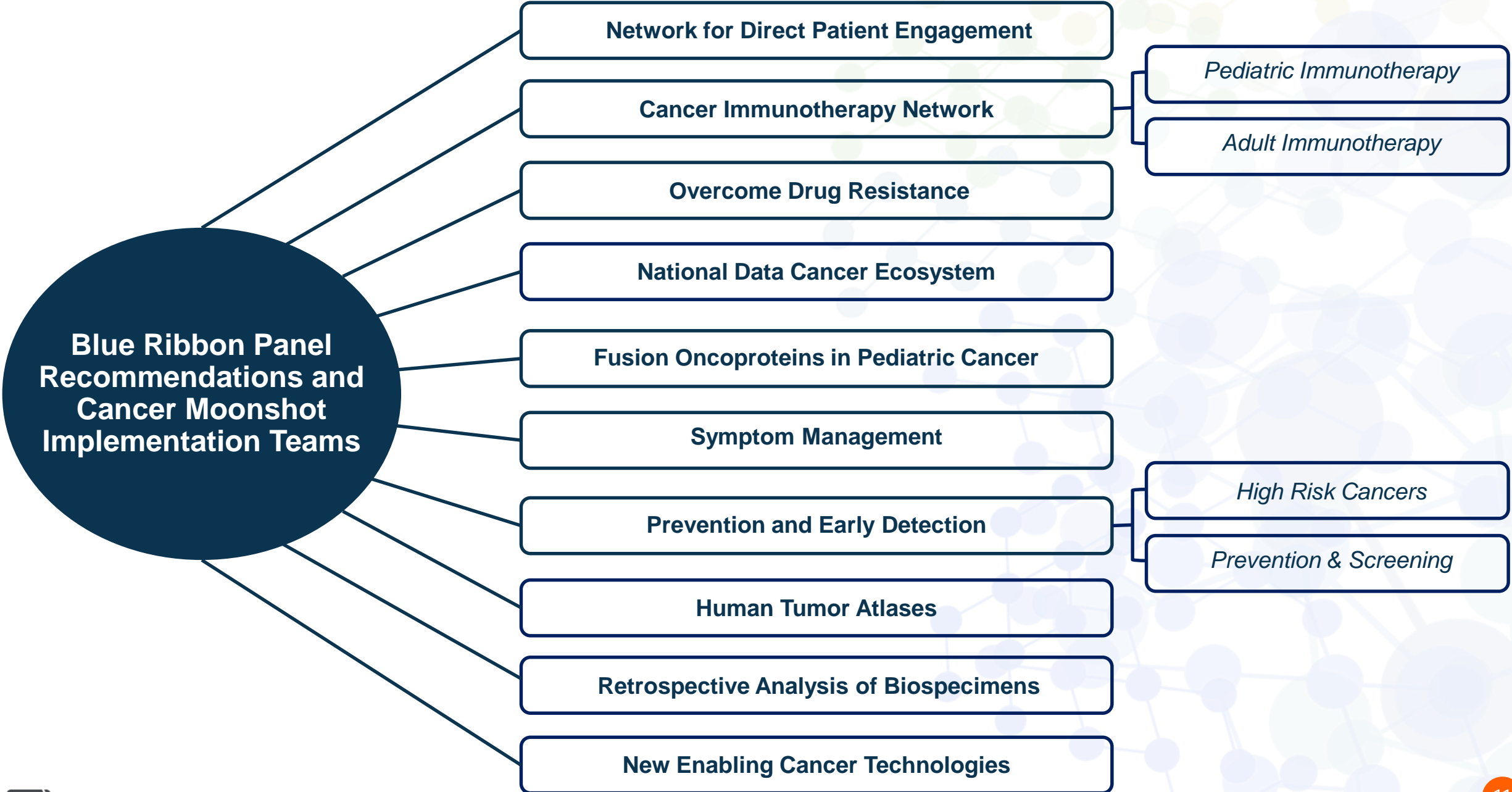
STAR Act - Childhood Cancer Survivorship, Treatment, Access, and Research Act of 2018 (Signed 6/18)

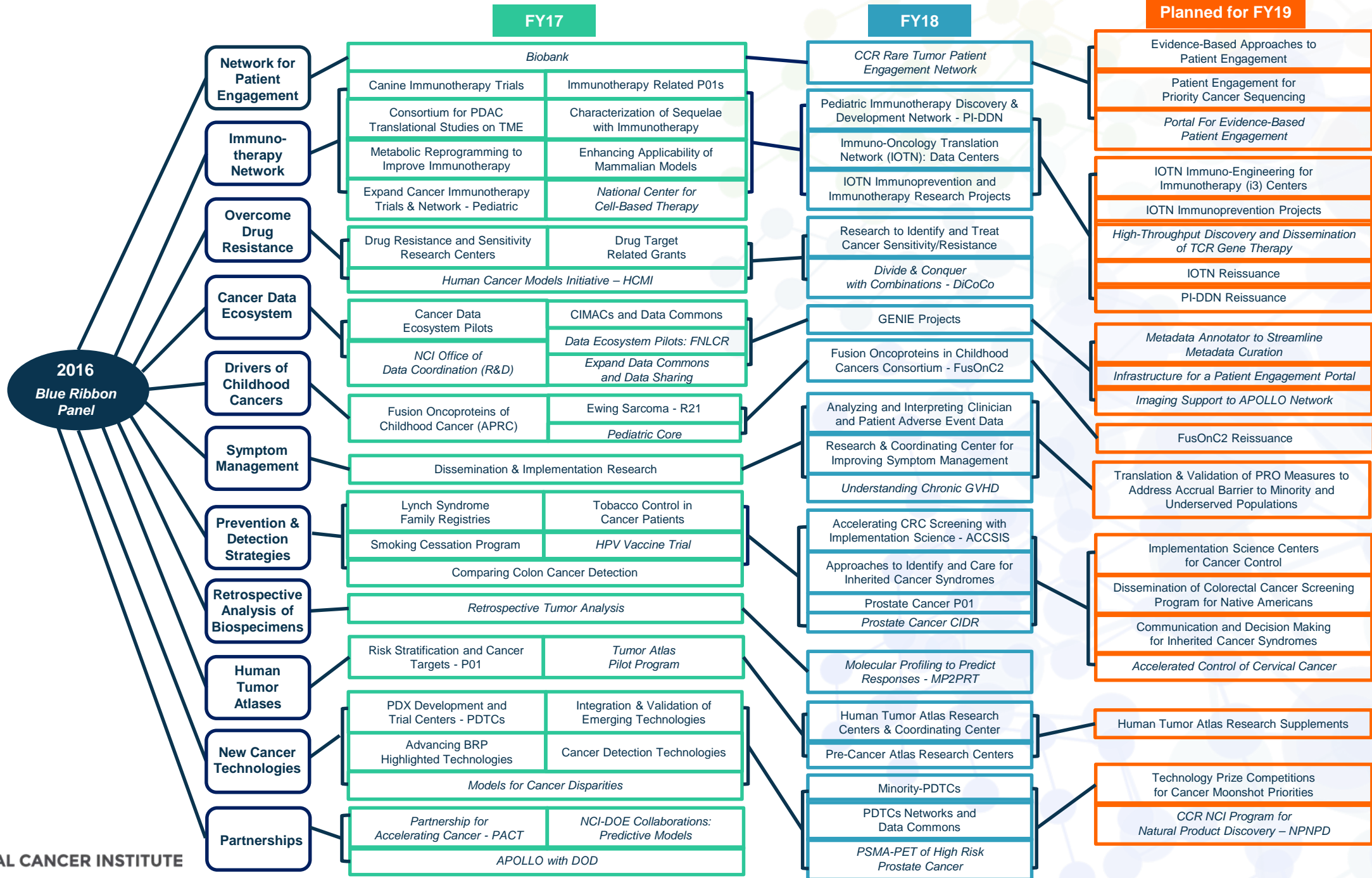
- Provisions directed toward NIH/NCI focus on childhood, adolescent, and young adult biospecimen collection and resources, as well as pediatric cancer survivorship research.
- Addresses inclusion of pediatric oncology expertise.

RACE Act - Research to Accelerate Cures and Equity for Children Act (Signed 8/17)

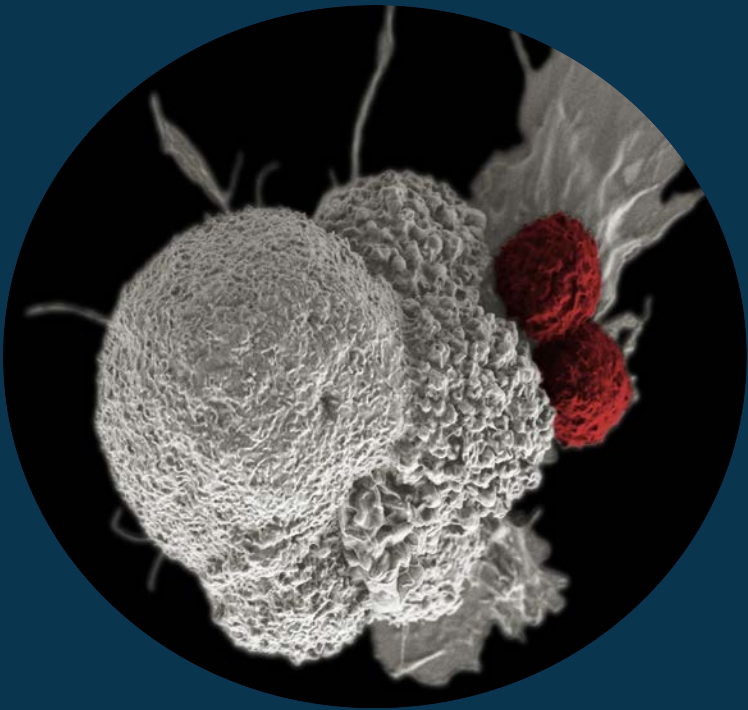
- If molecular targets of a drug under FDA review is “substantially relevant” to the pediatric population, FDA can require a pediatric study plan for dosing and activity-seeking studies.
- The new provisions require FDA, in consultation with NCI, to develop and maintain list of relevant and non-relevant targets by August 2018.
- In April 2018, NCI issued an RFI to collect input in addition to these two meetings. FDA held public meetings in May and June 2018.

Cancer Moonshot





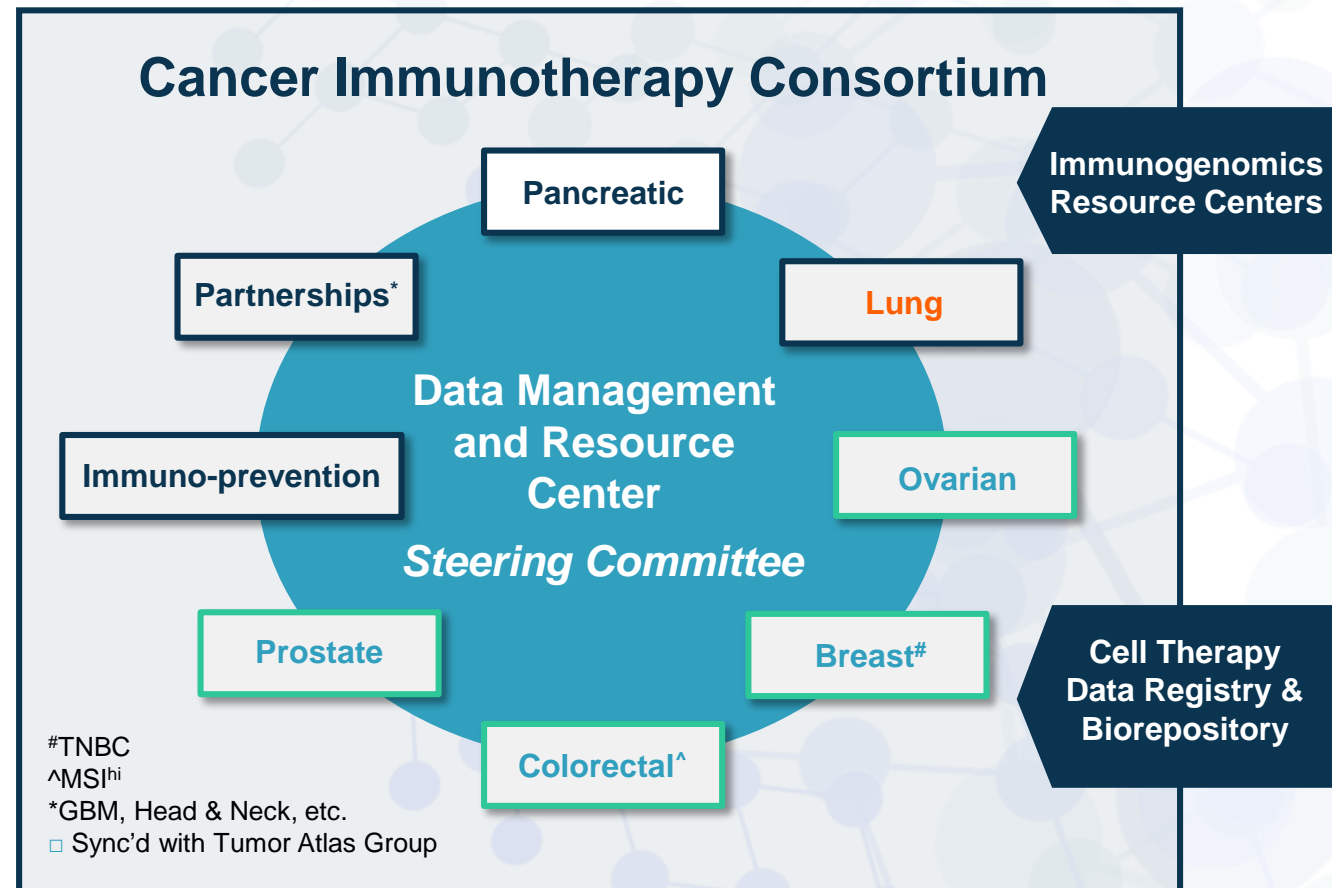
A Few of the 2018 Cancer Moonshot Initiatives



- Immuno-Oncology Translation Network
- Fusion Oncoproteins in Childhood Cancers Consortium
- Approaches to Identify and Care for Individuals with Inherited Cancer Syndromes
- Human Tumor Atlas Network
- Accelerating CRC Screening & Follow-up through Implementation Science (ACCSIS)

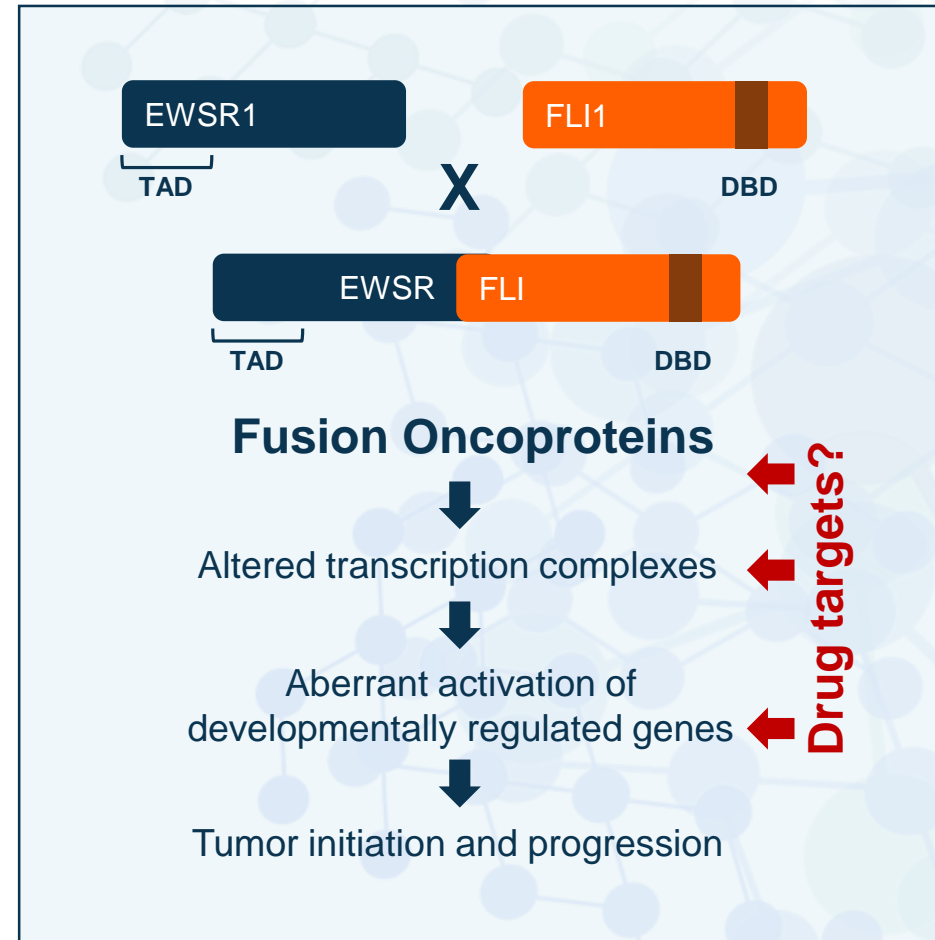
Immuno-Oncology Translational Network (IOTN)

- **Recommendation:** Accelerate translation of basic discoveries to clinical applications to improve immunotherapy outcomes for both “hot” and “cold” cancers
- **Implementation:** Leverage the expertise and resources of a collaborative *network* of investigators focused on improving immunotherapy approaches
- The IOTN *collaborates* with other NCI Programs:
 - PREVENT, Early Clinical Trials, and ETCTN
 - Cancer Immunotherapy Trials Network
 - CIMACs and Data Commons Network
 - Canine Immunotherapy Trials
 - Pediatric Immunotherapy Discovery and Development Network



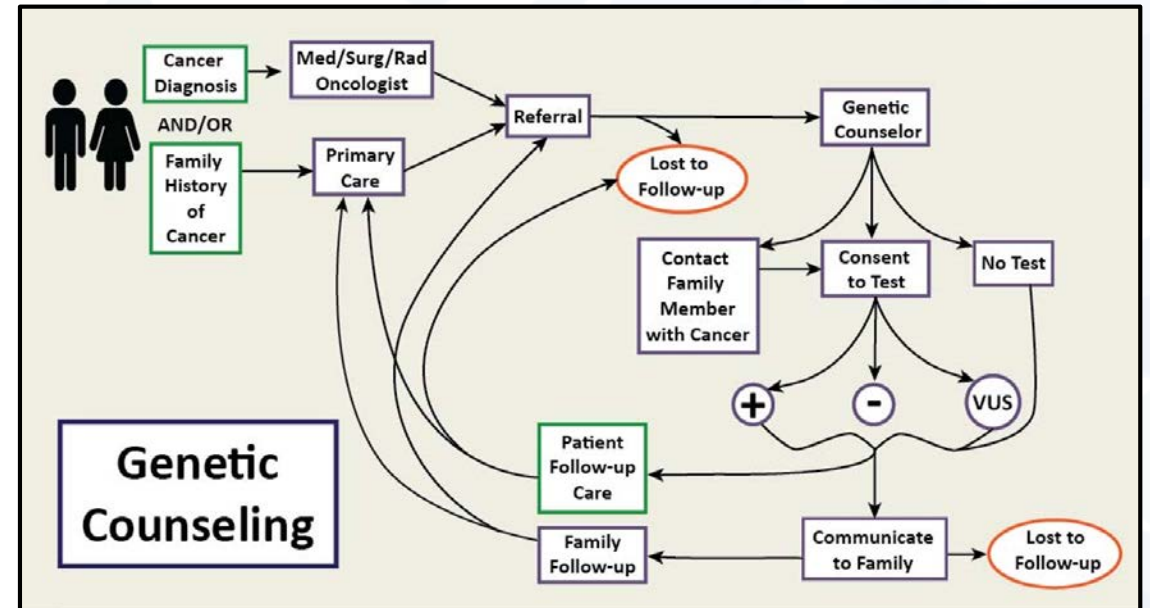
Fusion Oncoproteins in Childhood Cancers (FusOnC2) Consortium

- **Recommendation:** Improve our understanding of fusion oncoproteins in pediatric cancer.
- **Implementation:** Creation of a multi-disciplinary consortium of research teams taking a comprehensive approach to understanding the biology of fusion oncoproteins and developing therapeutics.
 - 3 Centers: Research Projects, Administrative Core, and Shared Resource Cores
- Focus on **high risk fusion-driven cancers** without existing effective targeted agents.



Approaches to Identify and Care for Individuals with Inherited Cancer Syndromes

- **Recommendation:** Improve prevention and early detection for individuals with an inherited predisposition and high risk for cancer.
- **Implementation:** Support collaborative, multidisciplinary research projects investigating the detection of hereditary cancers and delivery of care for high-risk individuals
 - Evidence-based services
 - Behavioral and psychosocial effects of genetic testing
 - Best practices for diagnostic and follow-up care
- Involves the development of sustainable approaches in **diverse** care settings and populations



Human Tumor Atlas Network (HTAN)

- **Recommendation:** Generate 3D and 4D atlases of tumors over time
- **Human Tumor Atlases**
 - Describe molecular, cellular, and physiological events across multiple scales
 - Enable predictive modeling
 - Span from premalignancy to metastasis
- **Implementation:** Create a collaborative *network* to build high-priority human tumor atlases to understand transitions in cancer
 - HTA and Pre-Cancer Research Centers
 - Coordinating Center
 - NCI CCR Project

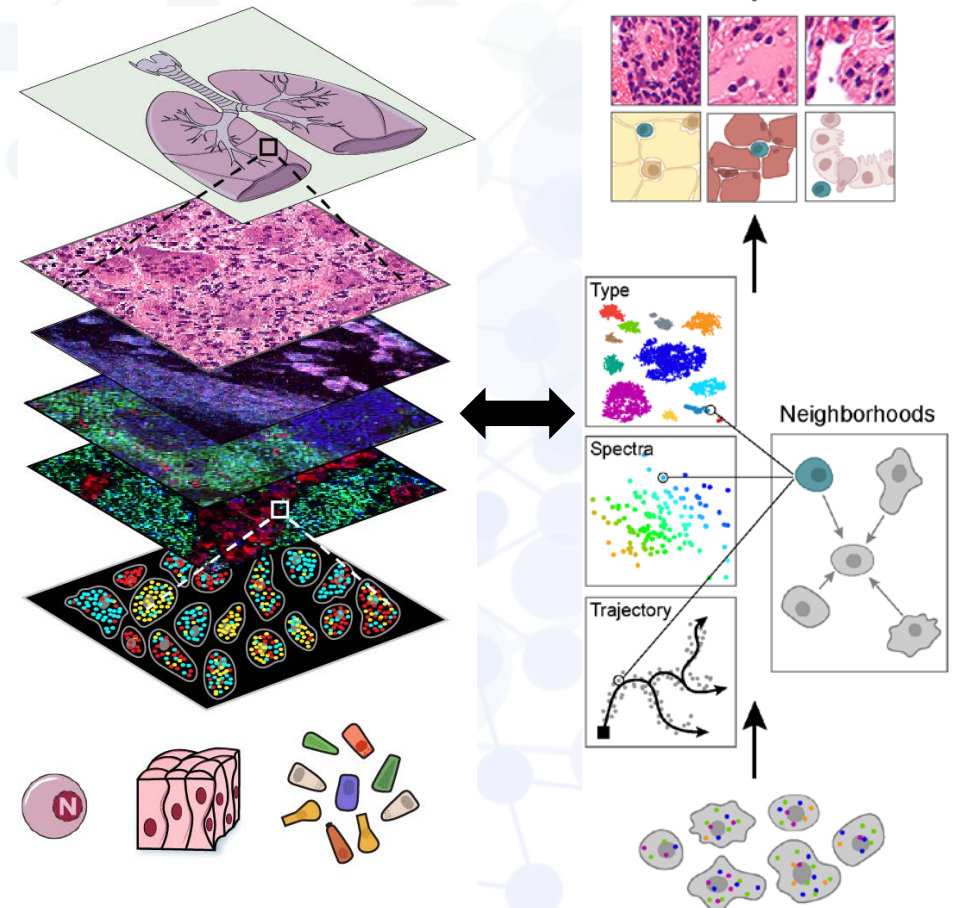


Figure from A. Regev and HTAPP Team

Accelerating Colorectal Cancer Screening and follow-up through Implementation Science (ACCSIS)

- **Recommendation:** Generate effective implementation strategies that substantially improve early cancer detection
- **Implementation:** Signature Trial to determine effective *implementation* approaches to increase colorectal cancer (CRC) screening
 - 3 Research Projects and a Coordinating Center
- Emphasis on addressing *disparities* in CRC screening and follow-up, including:
 - Underserved racial and ethnic minority populations
 - Rural and hard-to-reach populations
 - High-risk subgroups

ACCSIS Signature Trial

Phase 1 (UG3)



Feasibility and pilot testing of multilevel intervention among a target population

Phase 2 (UH3)



Comparative effectiveness trial of implementation strategies to increase CRC screening and follow-up

Rare Tumor Patient Engagement Network



Rare Tumor Patient Engagement Network

- Funded by the Cancer Moonshot.
- Build a national network to study selected rare pediatric and adult tumors and develop a network of clinical trials.
- Partnering with patient advocacy networks.
- Partnering with centers of excellence to broaden the reach and impact.

NCI-CONNECT

**Comprehensive Oncology Network
Evaluating Rare CNS Tumors**

**Leaders: Mark Gilbert, M.D.,
and Terri Armstrong, Ph.D.**

Aims to advance our understanding of adult rare central nervous system cancers by establishing and fostering patient-advocacy-provider partnerships and networks to improve approaches to care and treatment.

MyPART

**Moonshot Pediatric, Adolescent,
and Adult Rare Tumors Network**

**Leaders: Karlyne Reilly, Ph.D.,
and Brigitte Widemann, M.D.**

To increase patient and patient family involvement in rare tumor research and develop new therapies for rare pediatric and adult solid tumors through increased understanding of tumor biology and natural history

Learn more at ccr.cancer.gov/research/cancer-moonshot

Workforce Development: Research Specialist Award (R50)

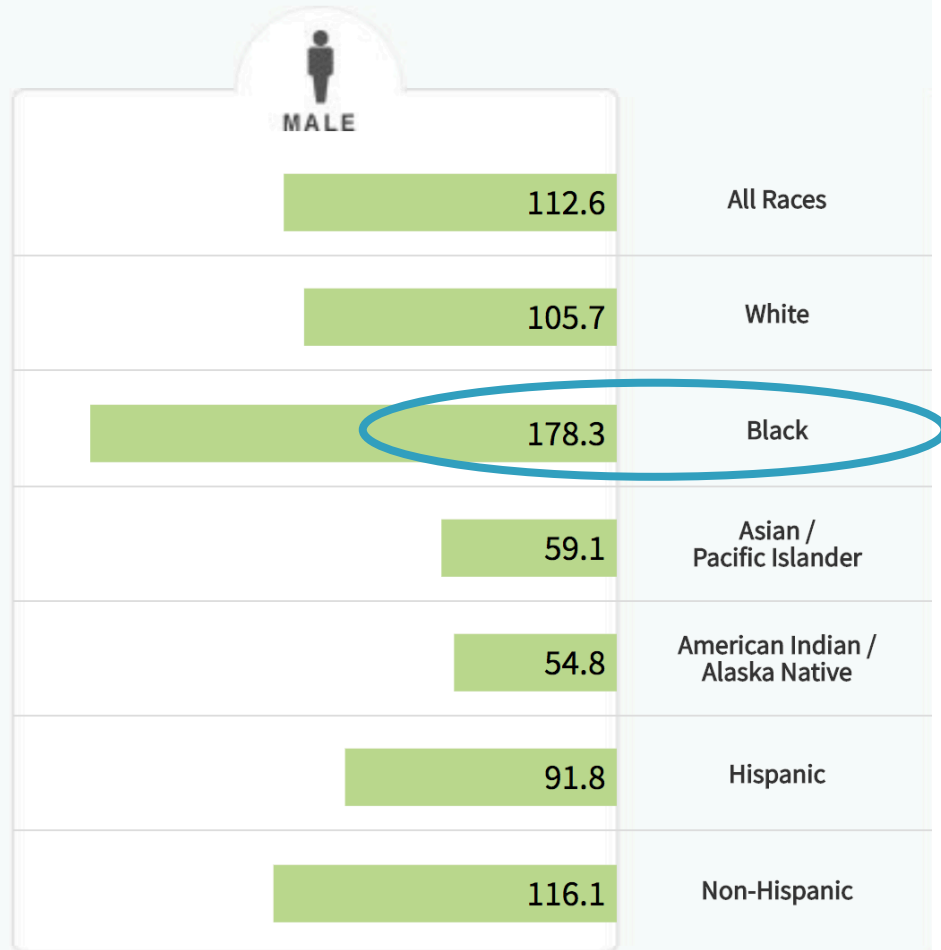
Research Specialist Award (R50)



- Intended to encourage the development of stable career opportunities for exceptional (non-tenure track) scientists who want to continue to pursue research within the context of an existing NCI-funded research program, but not serve as independent investigators
- The award is intended to provide salary support and sufficient independence to make this an attractive and sustainable career path
- **2 Funding Opportunity Announcements:**
 - **PAR-18-887** NCI Research Specialist (Core-based Scientist) Award (R50)
 - **PAR-18-888** NCI Research Specialist (Laboratory-based Scientist) Award (R50)

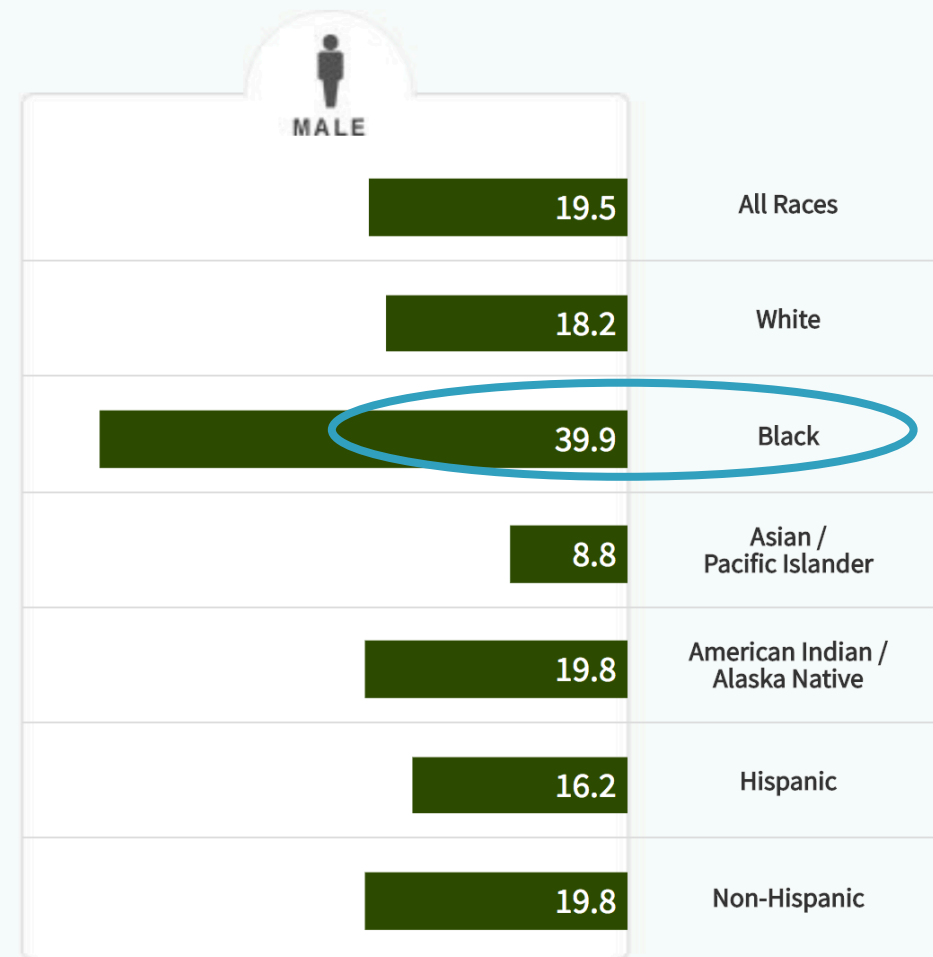
RESPOND Study

Incidence



SEER 18 2011-2015, Age-Adjusted

Mortality



U.S. 2011-2015, Age-Adjusted

RESPOND Study:

Research on Prostate Cancer in Men of African Ancestry

Defining the Roles of Genetics, Tumor Markers, and Social Stress

- This study will assess the impact of multilevel stressors and gene variants associated with aggressive and lethal prostate cancer which will help inform the etiology by which tumor aggressiveness arises and ideally help identify high-risk men for targeted prevention and treatment.
- The RESPOND Study builds on prior studies and years of collaborative efforts among investigators from institutions who are part of the African Ancestry Prostate Cancer Consortium (AAPC).
- The AAPC consists of 28 ongoing studies in the U.S. and globally. AAPC studies will contribute information and samples from African-American men.



RESPOND Recruitment Locations and Contacts



10,000 men will be newly recruited from cancer registries (California; Detroit, Michigan; New Jersey; Georgia; Louisiana; Texas; Florida)



NCI Program Director: Damali Martin, Ph.D., M.P.H., Epidemiology and Genomics Research Program, Division of Cancer Control and Population Sciences

- **Principal Investigator:** Christopher Haiman, Sc.D., University of Southern California (USC)
- **Project Lead Investigators**
 - John Carpten, Ph.D., USC
 - Scarlett Lin Gomez, Ph.D., University of California, San Francisco
 - Christopher Haiman, Sc.D., USC

Tweets about RESPOND

 **U.S. News**   





Massive study aims to recruit 10,000 African-American men and solve the fatal prostate cancer puzzle. trib.al/u5cmZkU



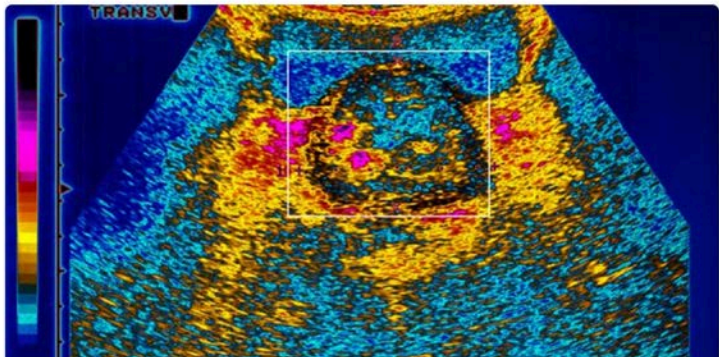
6:49 PM - 23 Jul 2018

7 Retweets 8 Likes 

 1  7  8 


 **NBC News**   





Black men are twice as likely to die of prostate cancer as white men. Government scientists said Tuesday that they are launching a study to try to discover why.







More black men die of prostate cancer. New study aims to find out why.
The National Institutes of Health study will look at genes and social stresses.
nbcnews.com


5:25 PM - 17 Jul 2018

82 Retweets 74 Likes 

 50  82  74 

 **O.C. Register**   

USC announces major study into prostate cancer among black men



USC announces major study into prostate cancer among bl...
USC's Keck School of Medicine is leading a \$26.5 million effort to conduct the first large-scale, multi-institutional study on black men with prostate cancer to better understand why they are...
ocregister.com

1:11 PM - 17 Jul 2018

 **KFYR-TV**   

Why do more black men die of prostate cancer?



More black men die of prostate cancer. New study aims to ...
The National Institutes of Health study will look at genes and social stresses.
nbcnews.com

4:04 PM - 17 Jul 2018



**NATIONAL
CANCER
INSTITUTE**

cancer.gov

cancer.gov/espanol