Update from Acting NCI Director

Douglas R. Lowy Acting Director, National Cancer Institute National Institutes of Health

CTAC Meeting July 12, 2017



NCI APPROPRIATIONS 2013-2017 (in billions)



Importance of Research Supported by NCI's Regular Appropriation (1)

- Largely non-overlapping with Cancer Moonshot research activities
- Some ongoing examples:
 - Training the next generation of investigators
 - Investigator-initiated research
 - Most clinical trials and cancer cohorts
 - PMI Oncology
 - RAS initiative

K08 Award: Expanded Criteria & Increased Support

- Increase flexibility to applications from physician-scientists:
 collapse K08 & K23
- Increase salary levels: up to \$185K for 100% time
- Increase research support: up to \$50K

Number of R01s/R35s Awarded



| | FY13 | FY14 | FY15 | FY16 |
|---------------------------------|------|------|------|------|
| Unsolicited R01s | 582 | 578 | 623 | 650 |
| R35s | | | 43 | 35 |
| Total Unsolicited | 582 | 578 | 666 | 685 |
| | | | | |
| RFA R01s | 29 | 51 | 12 | 45 |
| Total Solicited and Unsolicited | 611 | 629 | 678 | 730 |

Percent R01 and R21 Awards to ESI's & NI's (FY13-FY16)

| | FY13 | FY14 | FY15 | FY16 |
|--------------------------------------|------|------|------|------|
| R01: All New Investigators | 25% | 25% | 20% | 24% |
| | | | | |
| R01: Early Stage Investigators | 16% | 15% | 11% | 13% |
| | | | | |
| R21: All New Investigators | 45% | 40% | 40% | 40% |
| | | | | |

Genomic Analysis of Breast Cancer in African-Ancestry Populations

- Goal: improve understanding of breast cancer in black women
- Compare cancer genomes of 20,000 black women with breast cancer to 20,000 white women with breast cancer
- Compare germ line of 20,000 black women with breast cancer to 20,000 black women without breast cancer
- Uses biospecimens from multiple cohort studies

Importance of Research Supported by NCI's Regular Appropriation (2)

- Some new initiatives:
 - National Cryo-Electron Microscopy Facility, FNLCR
 - FNLCR = Frederick National Laboratory for Cancer Research
 - https://www.cancer.gov/research/resources/cryoem
 - TMIST breast cancer screening trial
 - TMIST = Tomosynthesis Mammographic Imaging Screening Trial

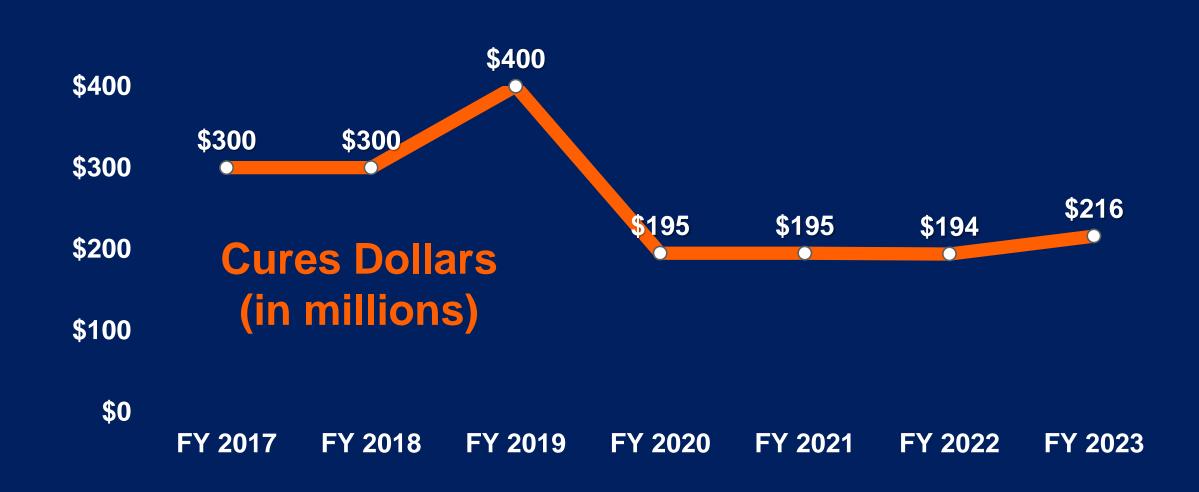
TMIST Breast Cancer Screening Trial

- Collaboration with ECOG-ACRIN
- Primary goal: Determine if cumulative rate of advanced breast cancer in women undergoing screening with tomosynthesis plus digital mammography is reduced compared to digital mammography alone
- RCT, 165,000 women 45-74
- Menopausal normal risk: biennial screens: 0, 24, 48 months
- Menopausal increased risk: annual screens: 0, 12, 24, 36, 48 months
- Biorepository

Initial Overall Goals of the Cancer Moonshot (January 2016)

- Accelerate progress in cancer; prevention, screening, treatment, mechanisms
 - From cutting edge research to wider uptake of standard of care
- Encourage greater cooperation and collaboration
 - Within and between academia, government, and private sector
- Enhance data sharing

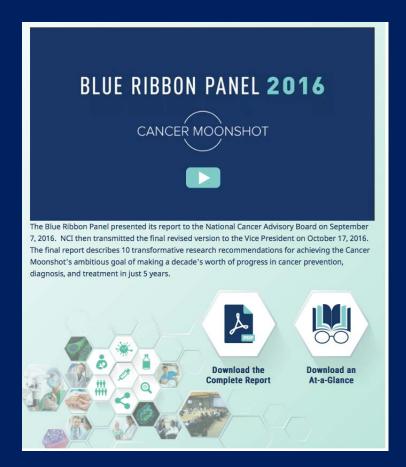
CANCER MOONSHOT: AUTHORIZED FUNDING



CANCER MOONSHOT: AUTHORIZED FUNDING

| Fiscal Year | Cures Dollars (in millions) | Estimated First Year Awards (in millions) |
|-------------|--------------------------------|---|
| 2017 | \$300 | \$140 |
| 2018 | \$300 | \$105 |
| 2019 | \$400 | \$60 |
| 2020 | \$195 | \$0 |
| 2021 | \$195 | \$0 |
| 2022 | \$194 | \$30 |
| 2023 | \$216 | \$25 |

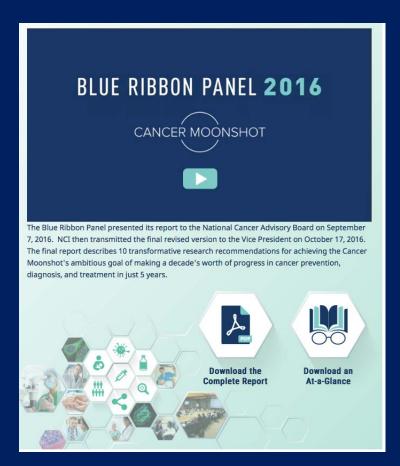
Blue Ribbon Panel Goals



available at: cancer.gov/brp

- Identify major scientific opportunities poised for acceleration by additional emphasis and funding
- Develop ~10 recommendations to be pursued through the Cancer Moonshot

Blue Ribbon Panel Recommendations



available at: cancer.gov/brp

- A. Network for direct patient engagement
- B. Cancer immunotherapy translational science network
- C. Therapeutic target identification to overcome drug resistance
- D. Creation of a national cancer data ecosystem
- E. Fusion oncoproteins in pediatric cancer
- F. Symptom management research
- G. Precision prevention and early detection
- H. Retrospective analysis of biospecimens from patients treated with standard of care
- I. Creation of human tumor atlas
- J. Development of new enabling technologies

FY17 Cancer Moonshot funding: Initial Implementation of Blue Ribbon Panel Recommendations

- Pediatric Fusion Proteins
 - APRC supplement program
 - core resources
- Technology
 - APRC supplement program
 - IMAT RFA
 - PDX development centers
- Immunotherapy
 - biomarker development labs RFA for adult and pediatric;
 - canine immunotherapy;
 - expand CITN to include pediatrics
 - Clinical center lab
 - Autoimmune sequelae collaboration with NIAID

- Therapeutic resistance RFA
- Retrospective risk stratification resource development
- Human tumor atlas
 - Pilot projects
- Prevention and Early Detection
 - HPV vaccine trial
- Implementation Science
 - Symptom management (oral cancer agents)
 - Reduce over-screening
 - Tobacco control supplements

One Dose HPV Vaccine Efficacy Trial: Moonshot

- Goal: Determine if a single HPV vaccine dose confer long-term protection in adolescent girls
- Four arm Non-inferiority RCT in Costa Rica: 1 & 2 doses Gardasil-9 (Merck), 1
 & 2 doses Cervarix (GlaxoSmithKline)
- Primary end-point: reduction in persistent HPV16/18 cervical infection
- Collaboration between Gates Foundation and NCI; companion immunogenicity trials in USA & Tanzania; HPV serology standardization project
- Potential impact if results are positive: Increase HPV vaccine uptake, save millions of dollars
- More info: Kreimer et al, JNCI 2015; Clinicaltrials.gov: Identifier NCT03180034

For new awards in FY18 – FY23: Cancer Moonshot Implementation Teams

- Implementation Teams aligned with BRP recommendations
- Composition: Staff from NCI & other Institutes
- Charge to each Implementation Team:
 - Develops and proposes initiatives for FY18 and beyond to help achieve a specific BRP Recommendation
 - Seeks input from cancer research community, including organizing workshops, etc.
 - Provides oversight and coordination of funded initiatives, including organizing meetings, providing supplements, etc.

FY18 Moonshot Initiatives: BSA Recommendations June 20-21, 2017

- Tolerability of Anti-cancer Treatment Using Clinician and Patient-reported Outcomes
- Improving Management of Symptoms Across Cancer Treatments (IMPACT)
- Collaborative Research Network for Fusion Oncoproteins and Childhood Cancers
- Pediatric Immunotherapy Translational Science Network (PI-TSN)
- Immuno-oncology Translational Network (IOTN)
- Human Tumor Atlas Network
- Approaches to Identify and Care for Individuals with Inherited Cancer Syndromes
- Moonshot Coordinating Center for Mechanisms of Cancer Drug Resistance and Sensitivity Network
- Accelerating Colorectal Cancer Screening and Follow-up through Implementation Science (ACCSIS)

Many potential collaborations

Possible collaborations with:

Other Institutes/Agencies

Private philanthropy

Pharma/biotech

Other countries

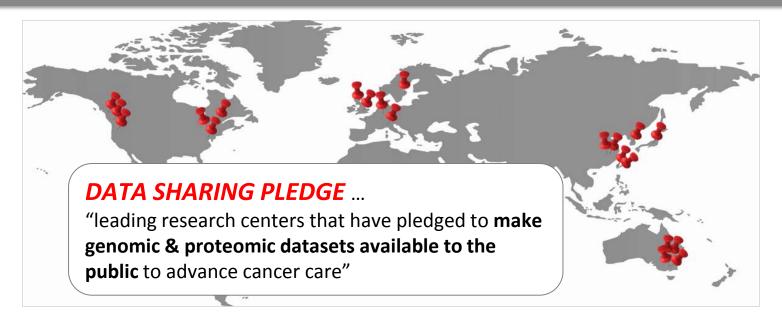
International donors

ICPC (International Cancer Proteogenome Consortium)

10 MOUs / **11** countries /

18 institutions





Australia

Team: Macquarie University, Children's Medical Research Institute, Garvan Institute of Medical Research, and Bioplatforms Australia Ltd.

Canada/Germany

Team: McGill University, University of Victoria, University of British Columbia, and Leibniz Institute for Analytical Sciences

China

Team: Shanghai Institute of Materia Medica, Chinese Academy of Science, and Fudan University

Japan

Team: National Cancer Center Japan

South Korea

Team: Korea Institute of Science and Technology

Sweden

Team: Lund University

Switzerland

Team: ETH Zürich

Taiwan

Team: Academia Sinica
Team: Chang Gung University

United Kingdom

Team: University of Manchester, and University of Dundee

United States

Team: NCI Clinical Proteomic Tumor Analysis Consortium

Norman E. (Ned) Sharpless

■ To be named NCI Director by the President



NIH NATIONAL CANCER INSTITUTE