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)

FY 2013: $4.82
FY 2014: $4.92
FY 2015: $4.95
FY 2016: $5.22
FY 2017: $5.39

+$300 million for Cancer Moonshot
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
<table>
<thead>
<tr>
<th></th>
<th>FY13</th>
<th>FY14</th>
<th>FY15</th>
<th>FY16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsolicited R01s</td>
<td>582</td>
<td>578</td>
<td>623</td>
<td>650</td>
</tr>
<tr>
<td>R35s</td>
<td>--</td>
<td>--</td>
<td>43</td>
<td>35</td>
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<tr>
<td><strong>Total Unsolicited</strong></td>
<td>582</td>
<td>578</td>
<td>666</td>
<td>685</td>
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<tr>
<td>RFA R01s</td>
<td>29</td>
<td>51</td>
<td>12</td>
<td>45</td>
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<tr>
<td><strong>Total Solicited and Unsolicited</strong></td>
<td>611</td>
<td>629</td>
<td>678</td>
<td>730</td>
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</tbody>
</table>
## Percent R01 and R21 Awards to ESI’s & NI’s (FY13-FY16)

<table>
<thead>
<tr>
<th></th>
<th>FY13</th>
<th>FY14</th>
<th>FY15</th>
<th>FY16</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>R01: All New Investigators</strong></td>
<td>25%</td>
<td>25%</td>
<td>20%</td>
<td>24%</td>
</tr>
<tr>
<td><strong>R01: Early Stage Investigators</strong></td>
<td>16%</td>
<td>15%</td>
<td>11%</td>
<td>13%</td>
</tr>
<tr>
<td><strong>R21: All New Investigators</strong></td>
<td>45%</td>
<td>40%</td>
<td>40%</td>
<td>40%</td>
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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

FY 2017 FY 2018 FY 2019 FY 2020 FY 2021 FY 2022 FY 2023

Cures Dollars (in millions)
# Cancer Moonshot: Authorized Funding

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Cures Dollars (in millions)</th>
<th>Estimated First Year Awards (in millions)</th>
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<tbody>
<tr>
<td>2017</td>
<td>$300</td>
<td>$140</td>
</tr>
<tr>
<td>2018</td>
<td>$300</td>
<td>$105</td>
</tr>
<tr>
<td>2019</td>
<td>$400</td>
<td>$60</td>
</tr>
<tr>
<td>2020</td>
<td>$195</td>
<td>$0</td>
</tr>
<tr>
<td>2021</td>
<td>$195</td>
<td>$0</td>
</tr>
<tr>
<td>2022</td>
<td>$194</td>
<td>$30</td>
</tr>
<tr>
<td>2023</td>
<td>$216</td>
<td>$25</td>
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Blue Ribbon Panel Goals

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

available at: cancer.gov/brp
Blue Ribbon Panel Recommendations

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

available at: cancer.gov/brp
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.
• 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
DATA SHARING PLEDGE...
“leading research centers that have pledged to make genomic & proteomic datasets available to the public to advance cancer care”

**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