Update from NCI Deputy Director

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

CTAC Meeting
November 1, 2017
Dr. Sharpless: on board!
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
Continuing Resolution for Start of FY 2018

• Funding: October 1 - December 8
• Includes funding for Cancer Moonshot
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 2017

FY 2018
Appropriations Committee Activities – FY18

**House bill – July 2017**

- NIH = + $1.1 billion over FY17 enacted level
- NCI = + $82 million over FY17 enacted level
- Additional $300 million - 21st Century Cures Cancer Moonshot Funding

**Senate bill – September 2017**

- NIH = + $2.0 billion over FY17 enacted level
- NCI = + $169 million over FY17 enacted level
- Additional $300 million - 21st Century Cures Cancer Moonshot Funding
National Institutes of Health
Appropriations History*
(Dollars in Millions)

<table>
<thead>
<tr>
<th>FY 2017 Enacted Appropriation</th>
<th>FY 2018 President's Budget</th>
<th>FY 2018 House Allowance</th>
<th>FY 2018 Senate Allowance</th>
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<tbody>
<tr>
<td>$34,084</td>
<td>$26,604 -21.9% Decrease From FY 2017</td>
<td>$35,184 3.2% Increase Over FY 2017</td>
<td>$36,084 5.9% Increase Over FY 2017</td>
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*Includes 21st Century Cures funding
Importance of Research Supported by NCI’s Regular Appropriation

• Largely non-overlapping with Cancer Moonshot research activities

• A few ongoing examples:
  • Training the next generation of investigators
  • Investigator-initiated research
  • Most clinical trials and cancer cohorts
  • PMI Oncology
  • RAS initiative
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; PACT
  • 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
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.
<table>
<thead>
<tr>
<th>Moonshot Implementation Team</th>
<th>RFA</th>
<th>RFA Published</th>
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<tbody>
<tr>
<td>Network for Patient Engagement</td>
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<tr>
<td>Pediatric Immunotherapy Network</td>
<td>1) Pediatric Immunotherapy Discovery and Development Network (PI-DDN): Specialized Centers (U54)</td>
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<tr>
<td></td>
<td>2) Pediatric Immunotherapy Discovery and Development Network (PI-DDN)(U01)</td>
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<tr>
<td>Adult Immunotherapy Network</td>
<td>1) Immuno-Oncology Translation Network (IOTN): Cancer Immunotherapy Research Projects (U01)</td>
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<td></td>
<td>2) Immuno-Oncology Translation Network (IOTN): Cancer Immunoprevention Research Projects (U01)</td>
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<td></td>
<td>3) Immuno-Oncology Translation Network (IOTN): Data Management and Resource-Sharing Center (DMRC) (U24)</td>
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<td></td>
<td>4) Immuno-Oncology Translation Network (IOTN): Cellular Immunotherapy Data Resource (CIDR) (U24)</td>
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<tr>
<td>Target ID to Overcome Drug Resistance</td>
<td>1) Mechanisms of Cancer Drug Resistance and Sensitivity Coordinating Center (U24)</td>
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<td>National Cancer Data Ecosystem</td>
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<td>Fusion Oncoproteins</td>
<td>1) Fusion Oncoproteins in Childhood Cancers (FusOnC2) Consortium (U54)</td>
<td>RFA-CA-17-049</td>
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## Status of FY18 Moonshot RFAs (Cont.)

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<tr>
<th>Moonshot Implementation Team</th>
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<tr>
<td><strong>Symptom Management</strong></td>
<td>1) Analyzing and Interpreting Clinician and Patient Adverse Event Data to Better Understand Tolerability (U01)</td>
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<tr>
<td><strong>High Risk Cancers</strong></td>
<td>1) Approaches to Identify and Care for Individuals with Inherited Cancer Syndromes (U01)</td>
<td>RFA-CA-17-041</td>
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<tr>
<td><strong>Prevention and Screening</strong></td>
<td>1) Accelerating Colorectal Cancer Screening and follow-up through Implementation Science (ACCSIS)(UG3/UH3)</td>
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<td></td>
<td>2) Accelerating Colorectal Cancer Screening and follow-up through Implementation Science (ACCSIS) (U24)</td>
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<tr>
<td><strong>Retrospective Analysis of Biospecimens</strong></td>
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<tr>
<td><strong>Generation of Human Tumor Atlases</strong></td>
<td>1) Human Tumor Atlas Research Centers (U2C)</td>
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<td>2) Pre-Cancer Atlas (PCA) Research Centers (U2C)</td>
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<td></td>
<td>3) Human Tumor Atlas Network Data Coordinating Center (U24)</td>
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<tr>
<td><strong>Development of New Technologies</strong></td>
<td>1) Integration and Validation of Emerging Technologies to Accelerate Cancer Research (R33)</td>
<td>RFA-CA-17-023</td>
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Cancer Immune Monitoring and Analysis Centers (CIMACs)
Cancer Immunologic Data Commons (CIDC)

• Why CIMAC-CIDC network
  • To provide a standing, prefunded network of laboratories, along with a common data center, to perform biomarker assays and analysis for NCI-funded, early phase 1/2 clinical trials with immunotherapies, using standardized and state of the art assays
  • Data repository/center for biomarker results from CIMACs will foster a data integration/analysis platform for correlative studies within and across trials

• Funded under cooperative grant mechanisms (U24)
  • Current funding limited to early immunotherapy trials (phase I and phase II) under the NCI clinical trial networks or NCI grants (R01, SPORES, etc)
  • Covers comprehensive profiling for approximately 400 patient–timepoint per year

• Utilization of the CIMAC-CIDC resource is voluntary, but desired studies will require collaboration with CIMAC and approval by CTEP.

• FNLCR PD lab will collaborate with UCSF, Stanford, Mt. Sinai, MD Anderson, DFCI for assay development
Proposed CIMACs-CIDC Network Structure (Tentative)

- Each CIMAC is a multidisciplinary team (bioassays, statisticians, informatician, translational scientists, pathologists)
- Will be aligned with Clinical Trial Networks and Clinical trials – Collaboration in scientific planning, tissue accession, data analysis, and publication
- Triage of the work will be based on: Assay expertise; Overall workload; Established relationship with specific trials
- A given CIMAC may perform a specific assay for all CIMACs, depending on resource prioritization and expertise
Partnership to Accelerate Cancer Therapies (PACT)

- Public-private partnership: provides increased support for CIMAC immunotherapy network and related precompetitive immunotherapy research
  - **11 Pharmaceutical companies:** AbbVie, Amgen, Boehringer Ingelheim, Bristol-Meyers Squibb, Celgene, Genetech, Gilead Sciences, GlaxoSmithKline, Janssen, Novartis, Pfizer
- Governance: public-private, similar to FNIH Biomarkers Consortium
- Announced at October 12 Press Conference
Many potential collaborations

Possible collaborations with:
Other Institutes/Agencies
Private philanthropy
Pharma/biotech
Other countries
International donors
International Cancer Proteogenome Consortium

29 institutions / 11 countries / 10 MOUs

DATA SHARING PLEDGE ... “make genomic & proteomic datasets available to the public to advance cancer care”

ICPC Leadership Meeting
Sept 17, 2017
APOBEC3A is an oral cancer prognostic biomarker in Taiwanese carriers of an APOBEC deletion polymorphism

Chang Gung University
