

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

CTAC Meeting November 1, 2017



Dr. Sharpless: on board!

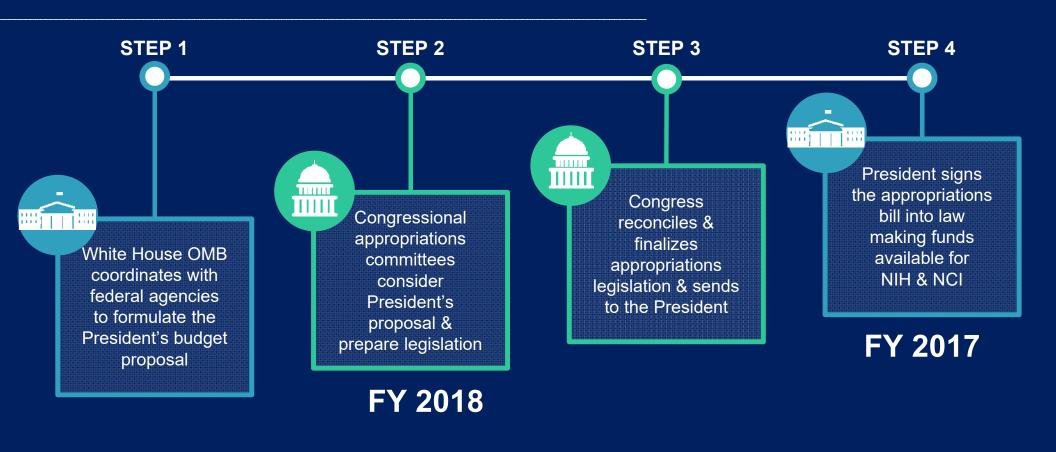
NCI APPROPRIATIONS 2013-2017 (in billions)



Continuing Resolution for Start of FY 2018

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

NCI/NIH BUDGET PROCESS FOR REGULAR APPROPRIATION



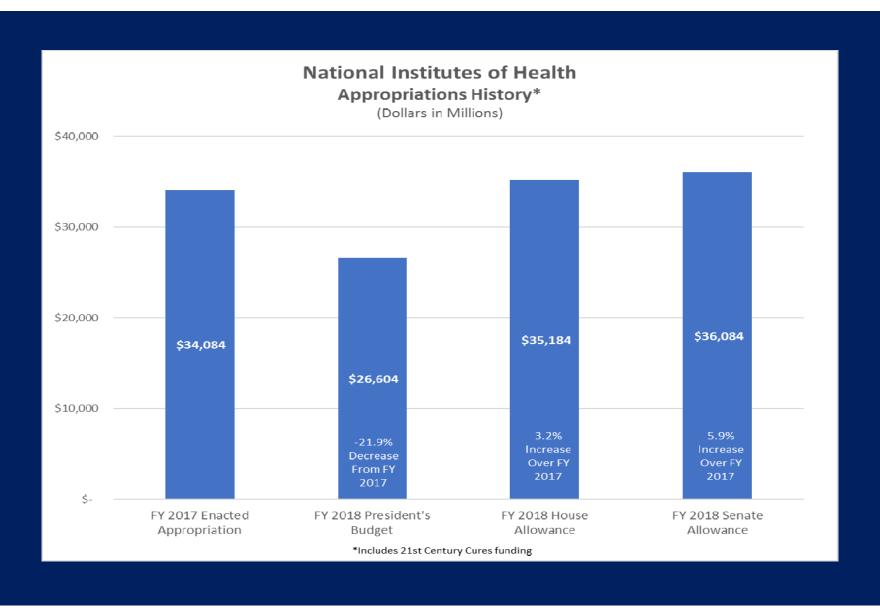
Appropriations Committee Activities – FY18

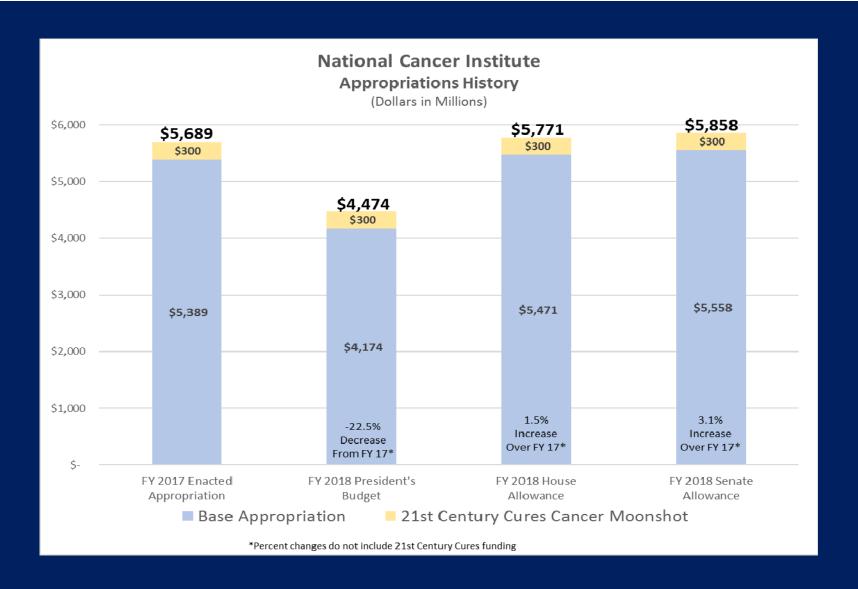
House bill —July 2017

- 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

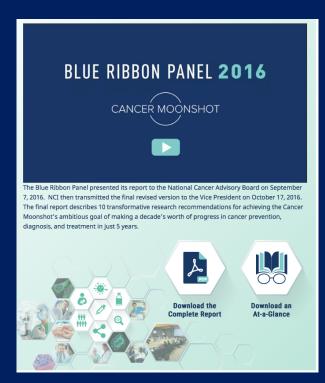




Importance of Research Supported by NCI's Regular Appropriation

- 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



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; 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.

Status of FY18 Moonshot RFAs

Moonshot Implementation Team	RFA	RFA Published
Network for Patient Engagement		
Pediatric Immunotherapy Network	Pediatric Immunotherapy Discovery and Development Network (PI-DDN): Specialized Centers (U54) Pediatric Immunotherapy Discovery and Development Network (PI-DDN)(U01)	
Adult Immunotherapy Network	1) Immuno-Oncology Translation Network (IOTN): Cancer Immunotherapy Research Projects (U01) 2) Immuno-Oncology Translation Network (IOTN): Cancer Immunoprevention Research Projects (U01) 3) Immuno-Oncology Translation Network (IOTN): Data Management and Resource-Sharing Center (DMRC) (U24) 4) Immuno-Oncology Translation Network (IOTN): Cellular Immunotherapy Data Resource (CIDR) (U24)	
Target ID to Overcome Drug Resistance	1) Mechanisms of Cancer Drug Resistance and Sensitivity Coordinating Center (U24)	
National Cancer Data Ecosystem		
Fusion Oncoproteins	1) Fusion Oncoproteins in Childhood Cancers (FusOnC2) Consortium (U54)	RFA-CA-17-049

Status of FY18 Moonshot RFAs (Cont.)

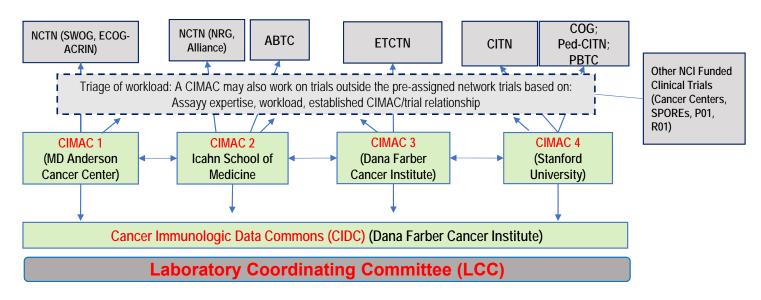
Moonshot Implementation Team	RFA	RFA Published
Symptom Management	1) Analyzing and Interpreting Clinician and Patient Adverse Event Data to Better Understand Tolerability (U01)	
High Risk Cancers	1) Approaches to Identify and Care for Individuals with Inherited Cancer Syndromes (U01)	RFA-CA-17- 041
Prevention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

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"







Taiwan Cancer Moonshot





Nat Commun. 2017 Sep 6;8(1):465; PMID: 28878238

