

# NCI Director's Report

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Norman E. Sharpless, M.D.

November 29, 2017

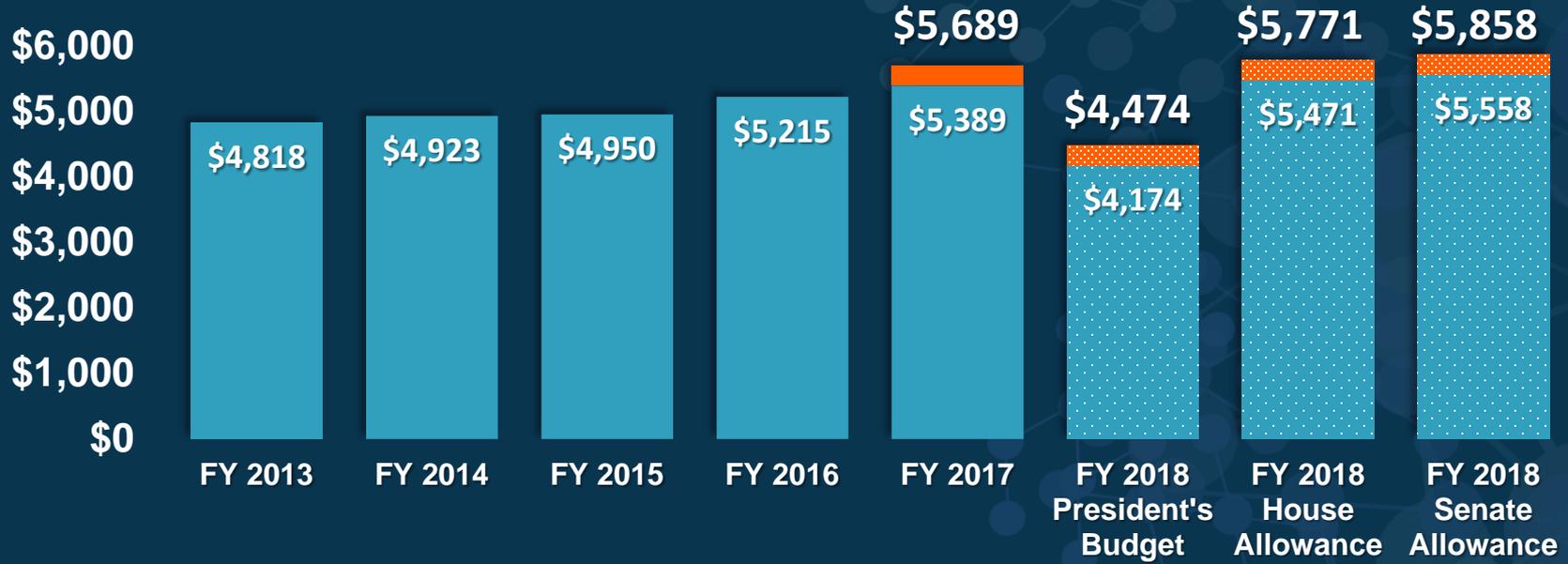


# NATIONAL CANCER INSTITUTE

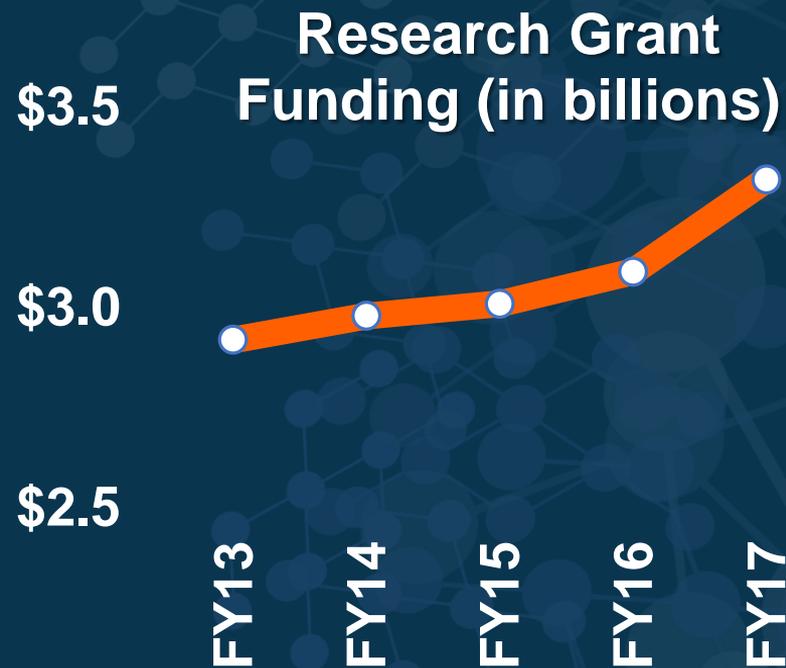
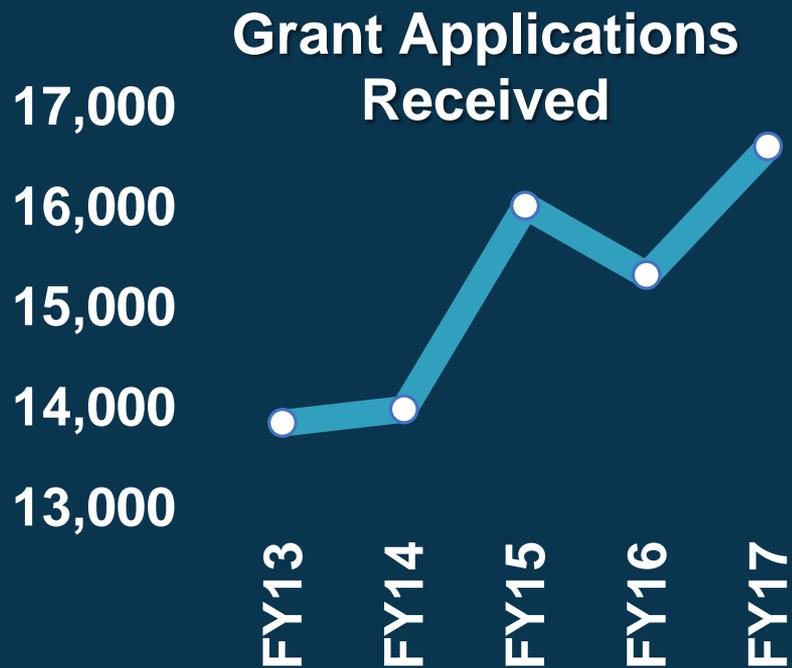
## SCOPE OF OUR WORK



# NCI Appropriations FY 2013-2018 (in millions)

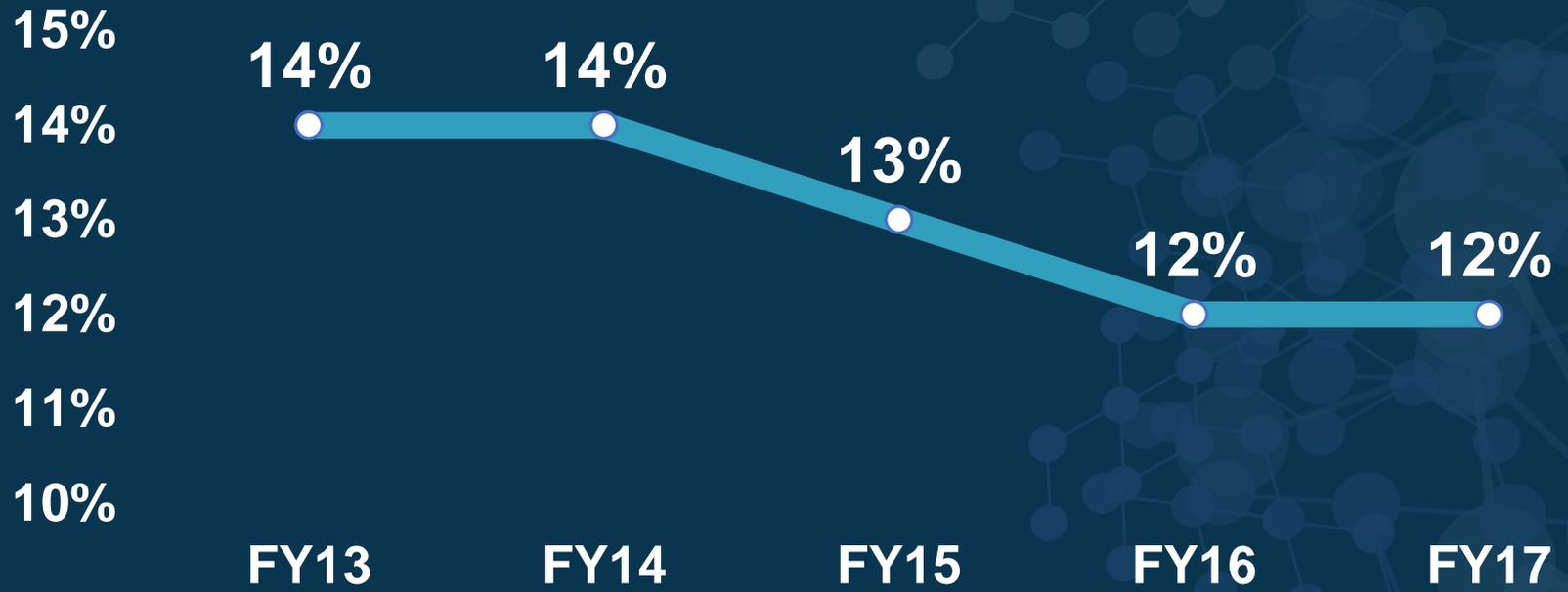


# Research Grants, FY 2013-2017



# Competing Research Project Grants (RPGs)\* Success Rate, FY 2013-2017

\*Does not include SBIR/STTR awards



# Budget Outlook

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- Continuing Resolution through December 8
- As always, we continue to be fiscally conservative
- Focus on early stage investigator (ESI) grants

# Welcome

Ethan Dmitrovsky, M.D.

President, Leidos Biomedical Research, Inc.

Director, Frederick National Laboratory for  
Cancer Research (FNLCR)



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# Updates from the NCI Office of the Director

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Douglas R. Lowy, M.D.



Dinah S. Singer, Ph.D.



James H. Doroshow, M.D.

# Updates from the NCI Office of the Director

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Douglas R. Lowy, M.D.

*Deputy Director*

November 29, 2017

# NCI Genomic Data Commons



The GDC consists of a 1) data exploration & visualization portal (DAVE), 2) data submission portal, 3) data analysis and harmonization system system, 4) an API so third party can build applications.

Source: NCI Genomic Data Commons: Grossman, Robert L., et al. "Toward a shared vision for cancer genomic data." *New England Journal of Medicine* 375.12 (2016): 1109-1112.

- The GDC makes available over 2.5 PB of data for access via an API, analysis by cloud resources, and downloading
- In Oct, 2017, the GDC was used by over 22,000 users and over 2.3 PB of data was downloaded.
- The GDC is a joint project between NCI, University of Chicago, OICR and Leidos.
- The GDC is based upon an open source software stack that is used to build other data commons.

# Systems 1 & 2: Data Portals to Explore and Submit Data

## Project

e.g. TCGA-GBM, Brain

## Primary Site

- Kidney 3
- Adrenal Gland 2
- Brain 2
- Colorectal 2
- Lung 2

21 More...

## Program

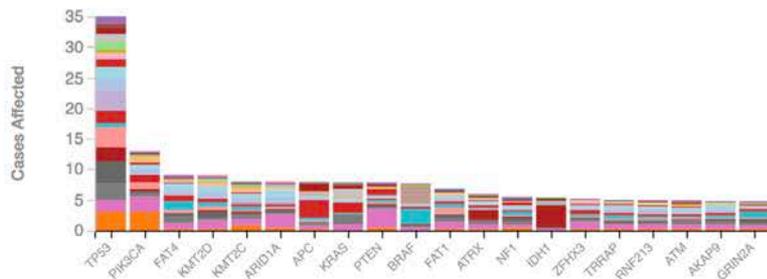
- TCGA 33
- TARGET 4

Clear Program Name IS TCGA AND Experimental Strategy IS RNA-Seq Open Query in Repository

### Top Mutated Cancer Genes in Selected Projects

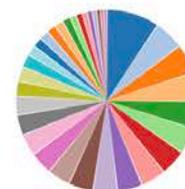
10,188 Unique Cases with Somatic Mutation Data

% of Cases Affected  # of Cases Affected



### Case Distribution per Project

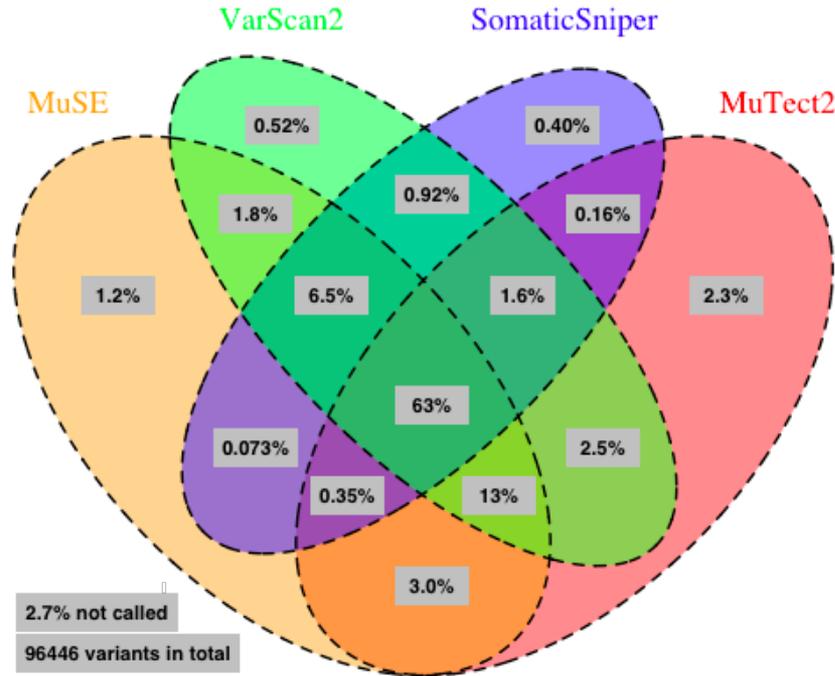
11,315 Cases across 33 Projects



Table

Graph

# System 3: Data Harmonization System To Analyze all of the Submitted Data with a Common Pipelines

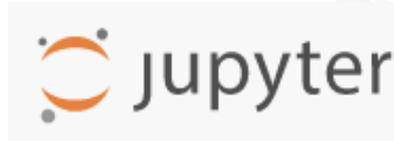


- MuSE (MD Anderson)
- VarScan2 (Washington Univ.)
- SomaticSniper (Washington Univ.)
- MuTect2 (Broad Institute)

Source: Zhenyu Zhang, et. al. and the GDC Project Team, Uniform Genomic Data Analysis in the NCI Genomic Data Commons, to appear.

## System 4: An API So Users and Third Party Software Developers Can Develop Applications and Notebooks to Create a Data Ecosystem

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- The GDC has a REST API so that researchers can develop their own applications.
- There are third party applications that use the REST API for Python, R, Jupyter notebooks and Shiny.
- The REST API drives the GDC data portal, data submission system, etc.

<https://gdc-api.nci.nih.gov/files/5003adf1-1cfd-467d-8234-0d396422a4ee?fields=state>

# Some Large Additions to the GDC

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- From Foundation Medicine: 18,000 cases uploaded and available
- From Genie (AACR consortium): 32,000 cases, in process
- From Palmetto: In discussion for open access for genomic and clinical data, to help develop evidence base for use of genomic profiling in clinical management

# K08 Award: Expanded Criteria & Increased Support

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- 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

# Lasker Clinical Research Scholars

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- Intramural-extramural partnership for clinical investigators
- Begin your independent research at the NIH Clinical Center, continue to develop it at an extramural institution (or remain at NIH)
- Up to 10 years of funding: 5-7 years at the Clinical Center, then up to 3 years at the extramural institution

# The Cancer Moonshot

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Dinah S. Singer, Ph.D.

*Acting Deputy Director*

November 29, 2017

# Cancer Moonshot: Status of FY2017 Initiatives

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## RFAs (10):

- PDX Development and Trial Centers (4)
- PDX Data Commons Center (1)
- Cancer Immune Monitoring and Analysis Centers (4)
- Cancer Immunologic Data Commons (1)
- Canine Immunotherapy Trials (5)
- Coordinating Center for Canine Immunotherapy (1)
- Consortium for Pancreatic Ductal Adenocarcinoma Translational Studies (5)
- PDAC Resource Center (1)
- Drug Resistance and Sensitivity (5)
- New Enabling Technologies (7)

# Cancer Moonshot: Status of FY2017 Initiatives (continued)

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## Partnerships, Contracts, Supplements (10):

- Partnership for Accelerating Cancer Therapies
- Gene Fusions in Pediatric Sarcomas
- Generation Of Human Tumor Atlases Pilot Program
- Costa Rica HPV Vaccine Trial
- Smoking Cessation Program
- Tobacco Control in Cancer Patients
- Retrospective Tumor Characterization Analysis
- Human Cancer Models Initiative
- APOLLO
- DOE-NCI Collaborations: Predictive Modeling

# Cancer Moonshot

## FY 2018 Funding Opportunities

Implementation Team	RFA Number	RFA Title	RFA Receipt Date
Pediatric Immunotherapy Network	<a href="#">RFA-CA-17-050</a>	Pediatric Immunotherapy Discovery and Development Network (PI-DDN)(U54)	12/19/17
	<a href="#">RFA-CA-17-051</a>	Pediatric Immunotherapy Discovery and Development Network (PI-DDN)(U01)	12/19/17
Adult Immunotherapy Network	<a href="#">RFA-CA-17-045</a>	Immuno-Oncology Translation Network (IOTN): Cancer	1/16/18
	<a href="#">RFA-CA-17-046</a>	Immuno-Oncology Translation Network (IOTN): Cancer Immunoprevention Research Projects (U01)	1/16/18
	<a href="#">RFA-CA-17-047</a>	Immuno-Oncology Translation Network (IOTN): Data Management and Resource-Sharing Center (DMRC) (U24)	1/16/18
	<a href="#">RFA-CA-17-048</a>	Immuno-Oncology Translation Network (IOTN): Cellular Immunotherapy Data Resource (CIDR) (U24)	1/16/18
Target ID to Overcome Drug Resistance	<a href="#">RFA-CA-17-044</a>	Mechanisms of Cancer Drug Resistance and Sensitivity: Coordinating Center (U24)	1/5/18
Fusion Oncoproteins	<a href="#">RFA-CA-17-049</a>	Fusion Oncoproteins in Childhood Cancers (FusOnC2) Consortium (U54)	11/15/17
Symptom Management	<a href="#">RFA-CA-17-052</a>	Analyzing and Interpreting Clinician and Patient Adverse Event Data to Better Understand Tolerability (U01)	1/18/18
	<a href="#">RFA-CA-17-042</a>	Research Centers for Improving Management of Symptoms During and Following Cancer Treatment (UM1)	1/17/18
	<a href="#">RFA-CA-17-043</a>	Coordinating Center for Research Centers for Improving Management of Symptoms During and Following Cancer Treatment (U24)	1/17/18
High Risk Cancers	<a href="#">RFA-CA-17-041</a>	Approaches to Identify and Care for Individuals with Inherited Cancer Syndromes (U01)	1/9/18
Prevention and Screening	<a href="#">RFA-CA-17-038</a>	Accelerating Colorectal Cancer Screening and follow-up through Implementation Science (ACCSIS)(UG3/UH3)	1/18/18
	<a href="#">RFA-CA-17-039</a>	Accelerating Colorectal Cancer Screening and follow-up through Implementation Science (ACCSIS): Coordinating Center (U24)	1/18/18
Retrospective Analysis of Biospecimens	<a href="#">RFA-CA-17-044</a>	Mechanisms of Cancer Drug Resistance and Sensitivity: Coordinating Center (U24)	1/5/18
Generation of Human Tumor Atlases	<a href="#">RFA-CA-17-034</a>	Human Tumor Atlas Research Centers (U2C)	1/18/18
	<a href="#">RFA-CA-17-035</a>	Pre-Cancer Atlas (PCA) Research Centers (U2C)	1/18/18
	<a href="#">RFA-CA-17-036</a>	Human Tumor Atlas Network: Data Coordinating Center (U24)	1/18/18

# Cancer Moonshot: FY2018 Intramural Concepts

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Rare Tumor Patient Engagement Network: Integration of patient support and research

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PSMA-PET Imaging of High Risk Prostate Cancer

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Divide and Conquer with Combinations (DiCoCo): A Master Trial in Lymphoma

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Understanding, Measuring and Preventing Chronic GVHD across the lifespan

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CCR Immunotherapy Center

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Population Screening for Cancer Predisposition Genes

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# Change in NCAB Meeting Dates

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Due to the large number of awards that will need to be made at the end of FY18 resulting from the Cancer Moonshot RFAs, the September NCAB meeting date has been moved to:

**August 14-15, 2018**



# Updates from the NCI Office of the Director

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James H. Doroshow, M.D.

*Deputy Director, Clinical and Translational Research*

November 29, 2017

# Partnership for Accelerating Cancer Therapies (PACT)

National Cancer Institute - Division of Cancer Treatment & Diagnosis

Cancer Immune Monitoring Analysis Centers (CIMACs)

Dana-Farber

Stanford

Mount Sinai

MD Anderson

AbbVie

Amgen

Boehringer  
Ingelheim

BMS

Celgene

Genentech

Gilead

GSK

Cancer Immunologic Data Commons (CIDC)

Dana-Farber  
Cancer  
Institute

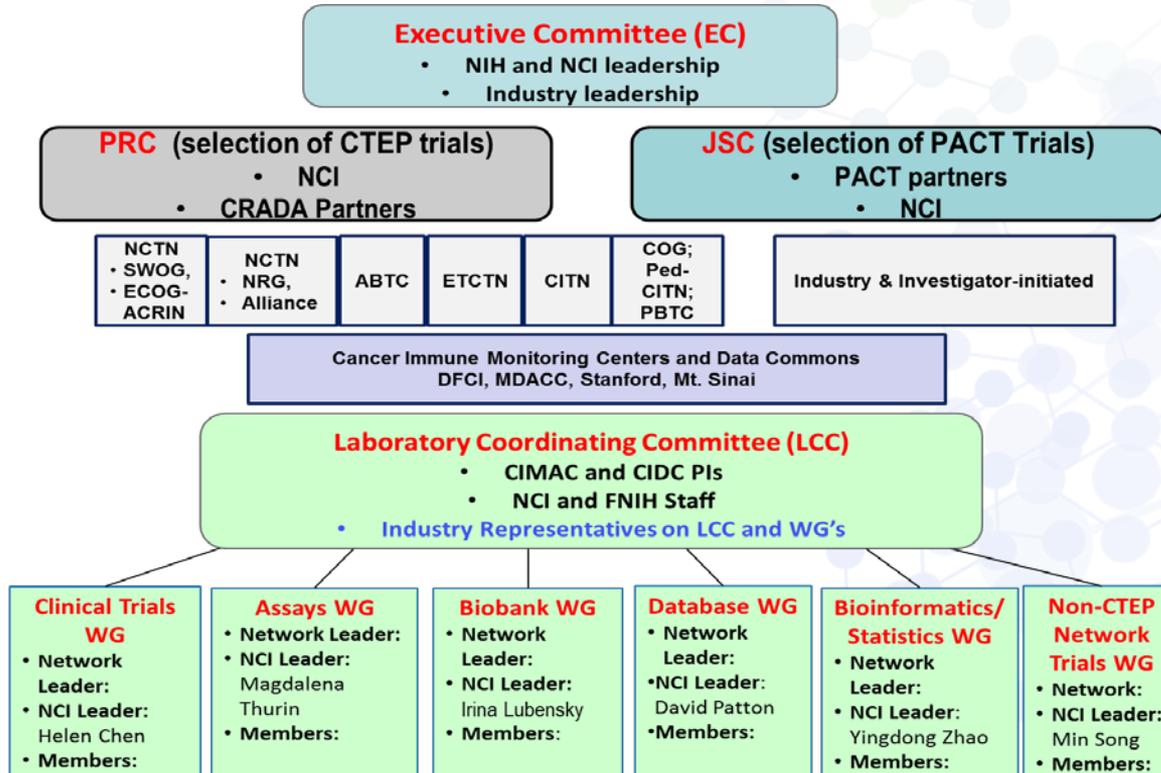
Janssen

Novartis

Pfizer

Sanofi

# Partnership for Accelerating Cancer Therapies (PACT)



# NCI Formulary

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- Leverage existing mechanisms to provide PIs with investigational agents for investigator held INDs
- Agent menu; 8 week turn-around time for Pharma review (approval or not) of proposals
- Agents provided for both clinical and pre-clinical studies
- Agreement terms standardized or pre-approved so as to substantially decrease the transactional costs of study initiation; NCI funds drug distribution and tracking of trials
- As of November, 2017: 27 agents from 9 companies:
- Agents: Alectinib; Atezolizumab; Bevacizumab; Blinatumomab; Cediranib; Cobimetinib; Durvalumab; Ensartinib; Ipilimumab; Larotrectinib; Mogamulizumab; Nivolumab; Obinutuzumab; Olaparib; Pertuzumab; Prexasertib; Savolitinib; Selumetinib; Trastuzumab; Tremelimumab; Vemurafenib; Vismodegib; Vistusertib; AZD1775; AZD5069; AZD5363; AZD6738
- Companies: Bristol-Myers Squibb; Eli Lilly; Genentech; Astra-Zeneca; Kyowa Hakko Kirin; Loxo; Xcovery; Amgen; Syntrix
- Multiple projects now in various phases of the approval process

# NCI Molecular Analysis for Therapy Choice (NCI-MATCH)

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## Update on 'Rare Variant Initiative'

- Patients with low frequency mutations (< 2%) where well qualified drugs/targets available
- Foundation Medicine, Caris Life Sciences, MDACC, MSKCC will notify treating physician at any of the  $\approx$  1100 MATCH sites when results of their NGS panel would make patient eligible for a MATCH treatment arm
- Results verified centrally by NCI-MATCH OncoPrint<sup>®</sup> assay
- Request for proposals from other NGS providers posted August 2, 2017 in the Federal Register; due by January 31, 2018: Broaden the base of patients available to enroll in precision oncology studies

# NCI Molecular Analysis for Therapy Choice (NCI-MATCH): 11/16/2017

Time period	# enrolled	# first samples submitted	# first sample fail	# assay complete	# assigned to Rx	# enrolled on Rx
Total Pre Pause	794	739	116	645	54	27
Most Recent Week	0	0	0	1	0	0
Total Post Pause	5603	5223	425	4912	937	660
Overall Total Screening Cohort	<b>6396</b>	5962	544	5560	992	<b>689</b>
Total Outside Assay	<b>74</b>	36	2	68	59	<b>45</b>



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# Engaging with Advisory Boards

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NCAB

BSC

Basic Sciences

BSC

Clinical & Epi

NCRA

BSA

CTAC

FNLAC

PCP

# NIH Clinical Center

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- The CC is a national treasure, but has suffered from chronic underfunding
- NIH leadership is committed to the CC
- Need help from extramural community to increase census
- Two concepts:
  - Simplified program allowing extramural PIs to run trials in CC
  - Trials in CC when COI limits testing at the home institution

# New NCI Working Groups

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SBIR/STTR



Global Health



Big Data

# Challenge Awards

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- The White House is eager for the NCI to increase its use of scientific prizes to spur innovative research.
- NCI has used prizes in the past. This mechanism has some desirable features, but also presents challenges.
- The hardest part is coming up with a well-crafted challenge that addresses an important scientific problem.
- We will need ideas from the NCAB/BSA, your collective institutions, and the full community.

# Questions?



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**[www.cancer.gov](http://www.cancer.gov)**

**[www.cancer.gov/espanol](http://www.cancer.gov/espanol)**