NCI Director's Report

Norman E. Sharpless, M.D.

44th Meeting of Clinical Trials & Translational Research Advisory Committee March 17, 2021





Agenda

- 50th Anniversary of the National Cancer Act
- Cancer Moonshot Midpoint
- NCI Appropriations & Paylines
- COVID-19 Impacts and Activities
- Childhood Cancer Data Initiative
- Equity and Inclusion
- NCI Research Highlights





"The President and I stand with you. This is the fight of our lives, and we will never stop working to end this disease. And together, I know that we're going to go farther than ever before."

Dr. Jill Biden Virtual Visit to NCI February 3, 2021

I'd love to be the President to preside over the end of cancer as we know it. These are the folks in the House and Senate who would love to preside over cancer —the end of cancer as we know it.

> President Joe Biden Bipartisan Meeting on Cancer, Oval Office March 3, 2021

NCA-50 commemoration launched February 8









Cancer Moonshot



MOONSHOT PROGRESS 2017-2020

240

RESEARCH PROJECTS & INITIATIVES

Cancer Currents: An NCI Cancer Research Blog

The Cancer Moonshot: A Midpoint Progress Update

January 11, 2021, by Norman E. Sharpless, M.D., and Dinah Singer, Ph.D.

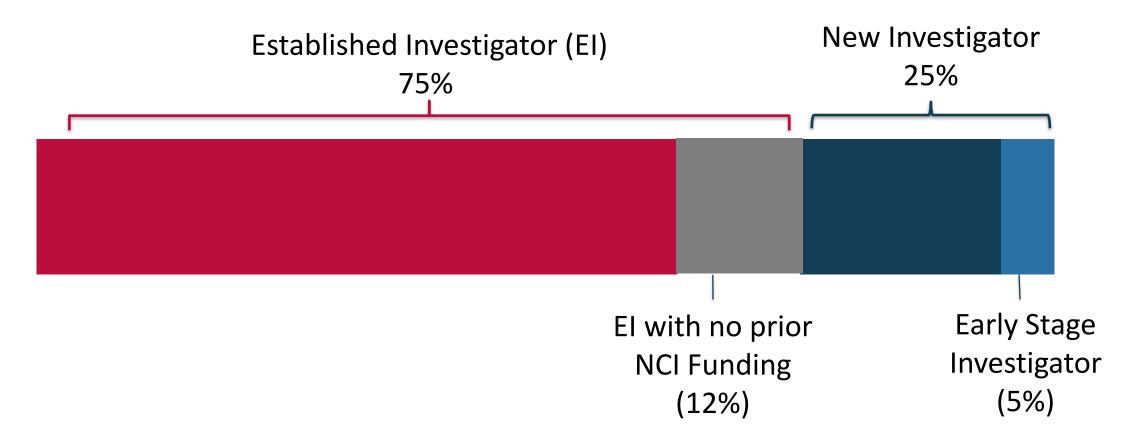


Cancer Moonshot Initiatives (2017-2020)

			0-1-1-000	ACE - CT-1-CH MILES	7	CCR Rare Tumor Patient	7	Personal Control of Data Workshop	h		Participant Engagement and
ſ	Network for Patient	V	Biobank (R&D)	#ClinicalTrialsSM Workshop	,	Engagement Network (IR)		Portal to Support		ri o	Cancer Genome Sequencing PE-CGS) Research Network
Engagemen	Engagement	I	Canine Immunotherapy Trials	Immunotherapy Related P01s		Immuno-Oncology Translation	1	Patient Engagement (R&D) IOTN Immuno-Engineering for Immunotherapy (i3) Centers	4		
			Pancreatic Cancer Microenvironment Network	Characterizing Sequelae w/ Immunotherapy (Admin Supp)		Network (IOTN): Data Centers IOTN Immunoprevention &			h		mmunity Liaison-based Patier ingagement for (Admin Supp)
1	Immuno therapy Network		Metabolic Reprogramming in Tumor Immunity R01	Enhancing Applicability of Mammalian Models		Immunotherapy Research Projects	ነ/	IOTN Immunoprevention Projects			Mitigating Immune-Related Adverse Events (irAEs)
	WANTE SECTION	1	National Center for Cell-Based Therapy (IR)		1	Research to Identify & Treat Cancer Sensitivity/Resistance (Admin Supp)	h	Discovery and Dissemination of TCR Gene Therapy (IR)		Mc	conshot Collaborative Meeting
Overcome Drug		Drug Resistance and	Drug Target Related Grants		MasterLymph: Precision Medicine to Improve DLBCL Therapy (IR & R&D)	$\sqrt{1}$	IOTN Reissuance	۱ بر	70	CR Gene Therapy Multicenter Trial Supplement (IR)	
ļ	Resistance		Sensitivity Research Network	(P01s & STTRs)]		Ϊ,	DRSN Supplements to Support Collaborations (Admin Supp)	1	C	ollaborative Cancer Moonshot
Cancer Data Ecosystem)	Support for GA4GH	Data Ecosystem (R&D)	7	GENIE Supplements Cancer Data Aggregator (R&D)	1	Imaging Data for APOLLO (R&D)	1	_	Projects (Admin Supp)
	_	(Admin Supps)	CIMAC-CIDC Network	V		1	Expand Data Commons (R&D)	- [[/r	,	Mechanisms of Cancer Drug Resistance (Comp Rev)	
	220000000000		Office of Data Sharing (R&D)	Expand Data Commons (R&D)	1 1	Pediatric Immunotherapy Discovery & Development Network	H	PI-DDN Reissuance	1/1		DRSN Coordinating Center
1	Intensify Research on)	F. i. S	D. 5-15- O (D8O)	1/	Fusion Oncoproteins in Childhood		FusOnC2 Reissuance	1\	4	(Admin Supp)
1	Childhood	M	Ewing Sarcoma R21 Fusion Oncoproteins of	Pediatric Core (R&D) Cancer Immunotherapy Trials		Cancers (FusOnC2) Consortium		PRO Measures to Address Accrual Barriers to Underserved (R&D)	1		De-Identification of Narrative
	Cancers		Childhood Cancer (APRC)	& Network - Pediatric		Assessing Tolerability of Treatment Using CTCAE & PRO-CTCAE	<u> </u>			C	finical Text Documents (R&D
Symptom					Improving Management of		STAR Act Improving Outcomes for Pediatric & AYA Cancer Survivors	IV.	-	PI-DDN Supplements FusOnC2 Supplements	
l	Management	J			1		symPtoms Centers (IMPACT)		1/	1	
,] }	Dissemination & Implementation Research Tobacco Control in Cancer Patients (Admin Supp)			cGVHD Symptom Measure (IR)	۱ با	Implementation Science Centers for Cancer Control (ISC3)	h		Optimizing Management and utcomes for Cancer Survivors
Prevention & Detection Strategies	H	Smoking Cessation R01	HPV Vaccine Trial (IR) etection (R01 & Admin Supp)		Accelerating CRC Screening with Implementation Science (ACCSIS) Approaches to Identify and Care for	h	Communication & Decision Making				
		A STATE OF THE PERSON NAMED IN COLUMN 2 AND ADDRESS OF THE PERSON				1	for Inherited Cancer Syndromes			Diffusion, Sustainability, and everaging of 3Cl (Admin Supp	
1		1	Retrospective Tumor Analysis (R&D)		1	Inherited Cancer Syndromes Prostate Cancer in Men. of African Ancestry (RESPOND)	1/	Accelerated Control of Cervical Cancer (Admin Supps)	r		
۱	Retrospective Analysis of	/					r	ACCSIS Reissuance	1		3D Technologies to Accelerate HTAN Efforts
1	Biospecimens		Integrative Oncogenomics of Multiple Myeloma P01	Tumor Atlas Pilot Projects (R&D)]	Dissemination of CRC Screening for	1	Approaches to Identify and Care for Inherited Cancer Syndromes Reissuance	1 /	-	Tradelorate TTT at Entre
1		1				Native Americans (Admin Supp)			1/	Γ	APHIROM Exploratory and
١	Human	1	PDX Development and	Integration & Validation of	1//	Control of Cervicel Cancer (R&D)	ľ	Human Tumor Atlas Research	1	140	Developmental Research CMI Next Gen Technology to
1	Atlases	リ	Trial Centers (PDTCs) Advancing BRP Highlighted	Technologies (R33/SBIR) Cancer Detection Technologies		Molecular Profiling to Predict Responses - MP2PRT (R&D)	7	(Admin Supp)		139	Next Gen Cancer Models
6	New	1	Technologies (APTRC Supp)	(SBIR/STTR Grants/Contracts)	'		۱/	APHIROM (Admin Supps)	h	N	lext Gen Models Supplement
1	Cancer Technologies		Models for Cancer Disparities (SBIR Contracts) Human Cancer Models Initiative – HCMI (R&D)			Human Tumor Atlas Research Centers & Coordinating Center	Y	SBIR Contracts for Innovative Tech	1/	/	ata Visualization Methods and Tool Development Projects
1	- community of						_	PDXNet Supplements Reissuance		-	ata Visualization Supplements
1	Partnerships	ips	Partnership for Accelerating	NCI-DOE Collaborations] \	Minority-PDTCs	-h/	Tech Prize Competition: Metadata			M-PDTC Supplements
П			Cancer Therapies (PACT)	(Pilots, JDACS4C, and ATOM)		PDXNet (Admin Supp)	1	Automation DREAM Challenge CCR NCI Program for	-1	8	SBIR Contracts for New Tech

25% of Moonshot Extramural Pls are New Investigators

343 Extramural Moonshot Pls (FY17 - FY20)



NCI Appropriations FY 2015 – 2021 (in millions) 21st Century Cures Act - orange Childhood Cancer Initiative - green



NCI Paylines for FY 2021

GRANT TYPE	PAYLINE				
R01 Grants for Established and New Investigators	11 th Percentile				
R01 Grants for Early- Stage Investigators (ESIs)	16 th Percentile				
R21 Exploratory Grants	9th Percentile				

Non-competing grants will be funded at 100%.



Funding from Congress Allows NCI to Raise Grants Payline

February 4, 2021, by Dr. Norman E. Sharpless



NCI COVID-19 activities

FOUNDATIONAL SEROLOGY

Serological Sciences
Network (SeroNet)

- 8 Centers of Excellence
- 13 Research Projects
- 4 Capacity Building Centers
- FNL Serology Lab & Network Coordinating Center

CLINICAL & TRANSLATIONAL SEROLOGY

Sero-protection Studies:

- Mount Sinai, University of Arizona
- NIH All of Us
- NCI SEER + Health Verity

COVID-19 Seroprevalence Studies Hub (SeroHub)

Antibody test performance evaluation, with FDA

Standard reference serum

Clinical trials for COVID-19 therapeutics

- Tocilizumab
- CD24Fc

SUPPORT FOR CANCER RESEARCH AND CARE AMID THE PANDEMIC

NCI COVID-19 in Cancer Patients Study (NCCAPS)

Flexibilities for grantees

Clinical trials adaptations

Modeling to predict long-term cancer outcomes

ADDITIONAL COVID-19 RESEARCH

- Excess Mortality Study
- Digital Health
 Solutions (with NIBIB)
- ACTIV (trans-NIH)

NCI COVID-19 in Cancer Patients Study (NCCAPS)

875

TRIAL SITES ACTIVATED IN

50

STATES + DC, PUERTO RICO, AND CANADA Special emphasis on minority, underserved and rural communities

Enrolled patients will be followed for 2 years

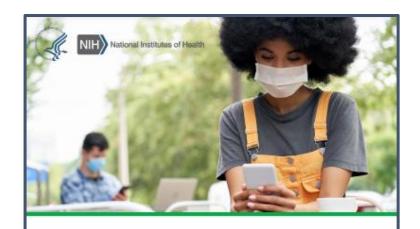
Now open to pediatric patients

Launched May 21
Conception to Launch in
6 weeks

Aims to enroll 2,000 patients across 1,000 sites in U.S.

974
PATIENTS
ENROLLED

NCI Research on Vaccine Hesitancy



COVID-19 Vaccination* Communication:

Applying Behavioral and Social Science to Address Vaccine Hesitancy and Foster Vaccine Confidence**

Wen-Ying Sylvia Chou, Ph.D., M.P.H., 'Caitlin E. Burgdorf, Ph.D.,' Anna Gaysynsky, M.P.H., 'Christine M. Hunter, Ph.D.'

- 1 National Center Institute, National Institutes of Health (NH)
- Office of Behavioral and Social Science Research, Division of Program Coordination, Planning, and Strategic Initiatives, NPT Although technically these are SAPS-CoV-2 vaccines, we refer to them as COVID-19 vaccines to be consistent with how most
- ** The content of this paper is based on what was known as of December 2020 negeting COVID-19 viscoines. Recommendations from this report may need to be adapted as new information becomes available.

"...communication about COVID-19 vaccines can benefit from drawing on the extant social and behavioral science literature about successful strategies to influence health decisions and behaviors."

NCI

Wen-Ying Sylvia Chou, Ph.D., M.P.H. Anna Gaysynsky, M.P.H.

NIH Office of Behavioral and Social Sciences Research Caitlin E. Burgdorf, Ph.D. Christine M. Hunter, Ph.D.



New CCDI Engagement Committee



Childhood Cancer
Data Initiative



Greg Aune, M.D.
UT Health San Antonio



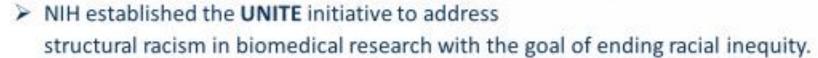
Brigitte C.
Widemann, M.D.
National Cancer
Institute

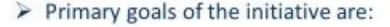


Lee J. Helman, M.D.
University of Southern California

NIH's Commitment to Ending Structural Racism

NIH is committed to instituting new ways to support diversity, equity, and inclusion, and identifying and dismantling any policies and practices that may harm our workforce and our science.





- U Understanding stakeholder experiences through listening and learning
- N New research on health disparities, minority health, and health equities
- I Improving the NIH culture and structure for equity, inclusion and excellence
- Transparency, communication, and accountability with our internal and external stakeholders
- E Extramural research ecosystem: changing policy, culture and structure to promote workforce diversity



nih.gov/ending-structural-racism



NCI Equity and Inclusion Program

EQUITY COUNCIL

Chair Ned Sharpless

Vice Chair
Paulette Gray

Mark Alexander Andrea Apolo Nelvis Castro Bob Croyle Montse Garcia-Closas Anne Lubenow Ji Luo Donna Siegle Dinah Singer Sanya Springfield

WORKING GROUP 1

Enhancing Research to Address Cancer Health Disparities **WORKING GROUP 2**

Ensuring Diversity of Thought and Background in the Cancer Research Workforce

WORKING GROUP 3

Promoting an Inclusive and Equitable Community at NCI

WORKING GROUP 4

Systematic Tracking and Evaluation of Equity Activities

WORKING GROUP 5

Communications and Outreach for Equity Activities

CO-CHAIRS

Jim Doroshow Worta McCaskill-Stevens Tiffany Wallace **CO-CHAIRS**

LeeAnn Bailey
Susan McCarthy
Glenn Merlino

CO-CHAIRS

Shannon Bell Paige Green Satish Gopal **CO-CHAIRS**

Michelle Bennett Doug Lowy **CO-CHAIRS**

Peter Garrett Angela Jones Anita Linde



Cancer Grand Challenges

Expressions of interest accepted until **April 22**, **2021**

- Understand how cells and tissues
 maintain "normal" phenotypes while
 harboring oncogenic mutations and how
 they transition to become a tumor
- Determine the potential benefits and risks of e-cigarette use
- Develop novel therapies to target unique features in solid tumors in children
- Systematically deliver macromolecules to intracellular targets for therapeutic benefit in cancer

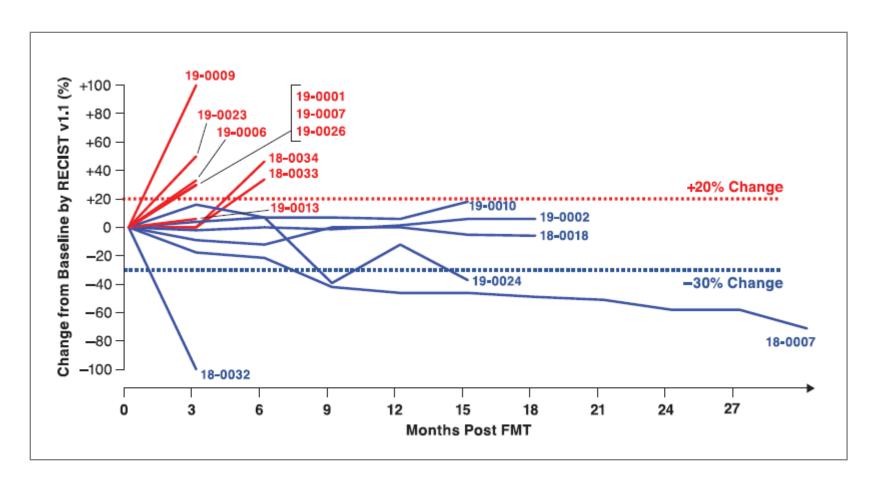


cancer.gov cancergrandchallenges.org

- Understand and exploit senescence to improve cancer treatment
- Determine how inflammation causes cancer
- Identify and target dormant cancer cells
- Understand the biology of extrachromosomal DNA (ecDNA) generation and action and develop approaches to target these mechanisms in cancer
- Understand and reverse cachexia and declining performance status in cancer patients

Fecal microbiota transplant in melanoma

Fecal microbiota transplant promotes response in immunotherapyrefractory melanoma patients



Science 05 Feb 2021: Vol. 371, Issue 6529, pp. 602-609 DOI: 10.1126/science.abb5920



USPSTF Updated Recommendations for Lung Cancer Screening – Released March 9, 2021

Adults aged **50 to 80** years who have a **20 pack-year smoking history** and currently smoke or have quit within the past 15 years:

- Screen for lung cancer with low-dose computed tomography (CT) every year.
- Stop screening once a person has not smoked for 15 years or has a health problem that limits life expectancy or the ability to have lung surgery.

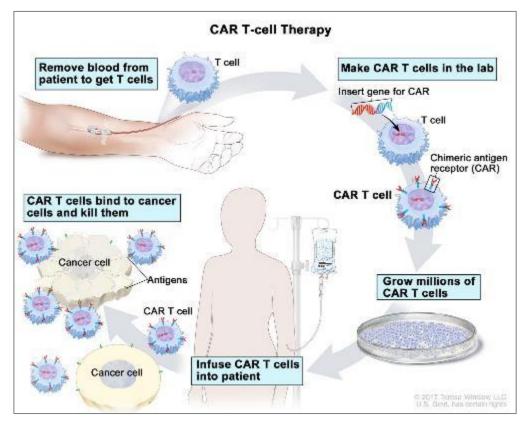
Previously 55 to 80 and 30 pack years

Recommendation based in part on modeling report from NCI's CISNET.



CAR T-cell manufacturing





https://www.cancer.gov/about-cancer/treatment/types/immunotherapy/t-cell-transfer-therapy



Discussion