Forum on
DRUG DISCOVERY,
DEVELOPMENT,
and TRANSLATION

NATIONAL
CANCER POLICY
FORUM

Optimizing Public-Private Partnerships for Clinical Cancer Research: A Workshop

Convened by the National Cancer Policy Forum in collaboration with the Forum on Drug Discovery, Development, and Translation

The National Academies NAS Building – Lecture Room
2101 Constitution Ave, N.W.
Washington, DC 20418

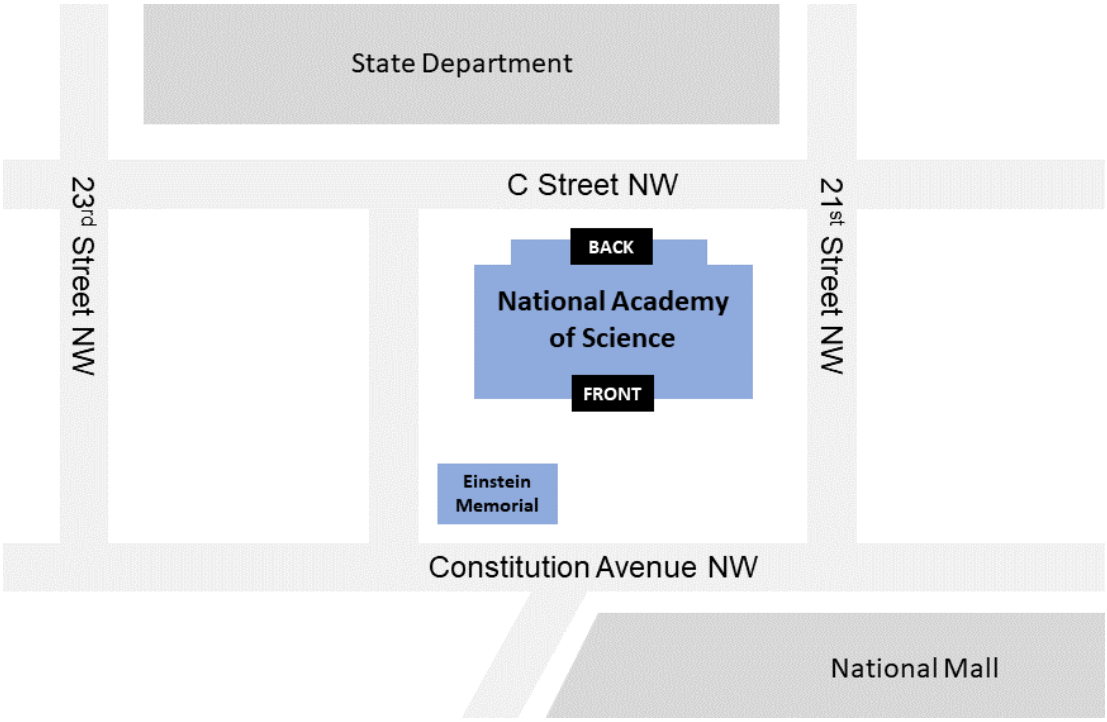
Link to view the live webcast:
Optimizing Public-Private Partnerships for Clinical Cancer Research: A Workshop | National Academies

NATIONAL ACADEMIES Sciences Engineering Medicine

NATIONAL CANCER POLICY FORUM

Workshop Location

The National Academies NAS Building – Lecture Room
2101 Constitution Ave, N.W.
Washington, DC 20418



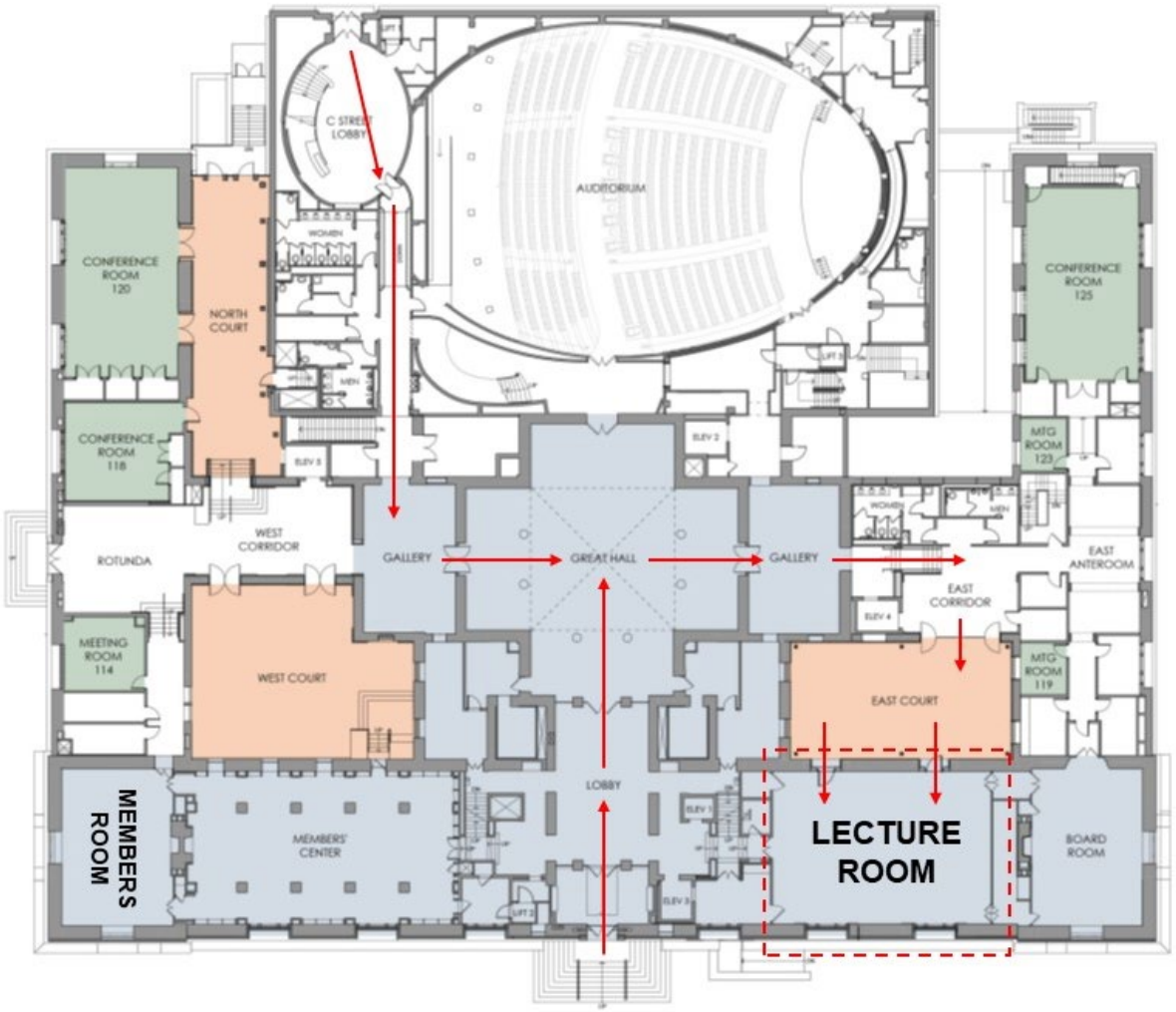
Uber/taxi/Lyft: The NAS building is across the street from The State Department (C Street entrance), or look for the Einstein statue (Constitution Ave. entrance)!

Entering from Constitution Ave NW: Please check in with the security guard at the desk and proceed straight into the Great Hall. Turn right and walk up the few stairs into the Gallery; The East Court/Lecture Room will be on your right.

Entering from C Street NW: Please check in with the security guard at the desk, walk through the lobby and hall, then turn left into the Great Hall. Turn left, walk up 3-4 stairs into the Gallery, and the East Court/Lecture Room is on your right.

See the National Academy of Sciences Building floor plan below.

C Street NW



Constitution Avenue NW

Forum on DRUG DISCOVERY, DEVELOPMENT, and TRANSLATION

NATIONAL CANCER POLICY FORUM

October 17, 2023

Dear Colleagues,

Welcome to the National Academies of Sciences, Engineering, and Medicine workshop, *Optimizing Public-Private Partnerships for Clinical Cancer Research*. This workshop is being convened by the National Cancer Policy Forum in collaboration with the Forum on Drug Discovery, Development, and Translation.

This workshop will examine opportunities to improve the care and outcomes for patients with cancer through public-private partnerships for clinical cancer research. Workshop participants will discuss the rationale for public-private partnerships to advance clinical cancer research; regulatory, policy, and data sharing considerations; best practices and lessons learned from prior public-private collaborations; and opportunities to embed clinical cancer research within the context of health care delivery.

We welcome your involvement in the workshop. Please use the microphones in the room or the chat box on our website to ask questions, and please mention your name and affiliation. The proceedings of the workshop will be published by the National Academies Press and may incorporate your comments and ideas. Archived presentations and videos from the workshop will also be available on the website.

We look forward to this important workshop.

Sincerely,

Roy S. Herbst, MD, PhD
Ensign Professor of Medicine
Chief of Medical Oncology
Deputy Director for Clinical Affairs
Yale Cancer Center and Smilow Cancer Hospital
Assistant Dean for Translational Research
Yale School of Medicine

Richard L. Schilsky, MD, FACP, FSCT, FASCO
Professor Emeritus
University of Chicago

Forum on DRUG DISCOVERY, DEVELOPMENT, and TRANSLATION

NATIONAL CANCER POLICY FORUM

Optimizing Public-Private Partnerships for Clinical Cancer Research: A Workshop October 17-18, 2023

National Cancer Policy Forum
Forum on Drug Discovery, Development, and Translation

Workshop Website
Lecture Room
NAS Building
2101 Constitution Avenue, NW
Washington, DC 20418

WORKSHOP AGENDA

TUESDAY, OCTOBER 17, 2023 EASTERN TIME ZONE	
7:30 am	**Breakfast and Registration** (30 minutes)
8:00 am	**Session 1: Rationale and Objectives for Public-Private Partnerships in the Clinical Cancer Research Enterprise** (2 hours) *Co-Moderators:* *Roy Herbst, Yale University* *Richard L. Schilsky, University of Chicago* **Welcome and Introductory Remarks** (20 minutes) • Roy Herbst, Yale University • Richard L. Schilsky, University of Chicago **Keynote Presentations** (30 minutes – 15 minutes each) • Julie Gerberding, Foundation for the National Institutes of Health • Dinah Singer, National Cancer Institute **Industry Perspective** (10 minutes) • Aida Habtezion, Pfizer Inc. *(participating virtually)* **Patient Advocacy Perspective** (10 minutes) • Ellen Sigal, Friends of Cancer Research **Food and Drug Administration Perspective** (10 minutes): • Richard Pazdur, FDA Oncology Center of Excellence **Panel Discussion** (40 minutes) Include speakers and: • Gail Eckhardt, Baylor College of Medicine • William Dahut, American Cancer Society, Inc.
10:00 am	**Break** (15 minutes)

10:15 am	**Session 2: Exemplars of Public-Private Partnerships in Clinical Cancer Research** (2 hours) *Co-moderators:* *Edith Perez, Mayo Clinic and Bolt Biotherapeutics* *Heidi Smith, Novartis Pharmaceuticals* **Examples of past and ongoing public-private collaborations in oncology** • **Lung Cancer Master Protocol (LungMAP)** (10 minutes) o Roy Herbst, Yale University • **PALbociclib CoLlaborative Adjuvant Study (PALLAS)** (20 minutes) o Erica Mayer, Dana-Farber Cancer Institute *(participating virtually)* o Prash Gopalakrishna, Pfizer Inc. *(participating virtually)* • **Pragmatica-Lung Cancer Treatment Trial** (20 minutes) o Karen L. Reckamp, Cedars Sinai o Harpreet Singh, FDA Oncology Center of Excellence **Panel Discussion** (1 hour 10 minutes) Include speakers and: • Stacey Adam, Foundation for the National Institutes of Health • Janet Dancey, Canadian Cancer Trials Group *(participating virtually)* • Vassilis Golfinopoulos, European Organisation for Research and Treatment of Cancer *(participating virtually)* • Meg Mooney, National Cancer Institute • Gwen Nichols, Leukemia and Lymphoma Society
12:15 pm	**Lunch** (45 minutes)
1:00 pm	**Session 3: Regulatory and Policy Considerations for Public-Private Partnerships for Clinical Cancer Research** (2 hours 10 minutes) *Co-moderators:* *Gideon Blumenthal, Merck* *Esther Krofah, Milken Institute and FasterCures* **National Clinical Trials Network (NCTN) Perspectives on Public-Private Partnerships for Cancer Research** (10 minutes) • James Doroshow, National Cancer Institute **FDA Perspective on Optimal Planning, Conduct, and Submission of Registration Intent Trials Conducted Through Public-Private Partnerships** (10 minutes) • Harpreet Singh, FDA Oncology Center of Excellence **Academia/Government Taskforce Perspective: How to Enhance Cooperation Between Agencies and Academia** (10 minutes) • Michael Morris, Memorial Sloan Kettering **Non-Profit Perspective: Patient Centeredness in Clinical Trial Design** (10 minutes) • Stacie Lindsey, Cholangiocarcinoma Foundation **Investor Perspective on Public-Private Partnerships for Cancer Research** (10 minutes) • Josh Bilenker, Treeline Biosciences

	Panel Discussion (1 hour 20 minutes) Include speakers and: • Jeff Allen, Friends of Cancer Research • Charles Blanke, Oregon Health & Science University • John Byrd, University of Cincinnati • Gail Eckhardt, Baylor College of Medicine
3:10 pm	**Break** (15 minutes)

3:25 pm	**Session 4: Enhancing Data Sharing for Public-Private Partnerships for Clinical Cancer Research** (2 hours 5 minutes)
	Co-moderators:
	Otis W. Brawley, Johns Hopkins University
	Kristen Rosati, Coppersmith Brockelman PLC
	
	Introduction (14 minutes)
	• Otis W. Brawley, Johns Hopkins University (7 minutes)
	• Kristen Rosati, Coppersmith Brockelman PLC (7 minutes)
	
	The Role of Government in Data Sharing (7 minutes)
	• Penny Burgoon, National Institutes of Health
	
	The Role of the Research Institution in Data Sharing (7 minutes)
	• Barbara Bierer, Harvard University
	
	The Role of the Patient in Data Sharing (14 minutes)
	• The Role of the Patent Advocate (7 minutes)
	  ○ Gwen Nichols, Leukemia and Lymphoma Society
	• The Role of Health IT in Data Sharing (7 minutes)
	  ○ Deven McGraw, Invitae/Ciitizen
	
	The Role of the Sponsor in Data Sharing (7 minutes)
	• Geoffrey Oxnard, Loxo Oncology, Eli Lilly
	
	The Role of the Funder in Data Sharing (7 minutes)
	• Tony Hickson, Cancer Research UK/Cancer Research Horizons
	
	The Role of Publications in Data Sharing (14 minutes)
	• Kirsten Bibbins-Domingo, Journal of the American Medical Association *(participating virtually)*
	• Eric Rubin, New England Journal of Medicine *(participating virtually)*
	
	Panel Discussion: Solutions for Facilitating Data Sharing (55 minutes)

5:30 pm	**Adjourn Day 1**
	Reception
WEDNESDAY, OCTOBER 18, 2023 EASTERN TIME ZONE	
7:30 am	**Breakfast and Registration** (30 minutes)
8:00 am	**Session 5: Embedding Clinical Cancer Research in Health Care Delivery** (2 hours) *Co-moderators:* *Neal Meropol, Flatiron Health* *Lawrence Shulman, University of Pennsylvania Abramson Cancer Center*

	Community Based Research Consortia (30 minutes)
	• Industry-Sponsored Consortium
	  ○ Melissa Johnson, Sarah Cannon Research Institute *(participating virtually)*
	• NCI Community Oncology Research Program Consortium
	  ○ Carolyn Y. Muller, University of New Mexico
	• American Society of Clinical Oncology Consortia
	  ○ Elizabeth Garrett-Mayer, American Society of Clinical Oncology
	
	Challenges and Opportunities for Public-Private Partnerships to Improve Access to Cancer Drugs and Reduce Outcome Disparities in Resource-Constrained Settings (10 minutes)
	• Larry Shulman, University of Pennsylvania Abramson Cancer Center
	
	Public-Private Partnerships to Support Post-Marketing Clinical Research in Routine Care Settings (10 minutes)
	• Neal Meropol, Flatiron Health
	
	Considerations for Industry Partnerships in Support of Health Care Delivery Research (10 minutes)
	• Craig Tendler, Johnson and Johnson *(participating virtually)*
	
	Panel Discussion (1 hour)
	Include speakers and:
	• Matthew Cooney, Tempus

10:00 am	**Break** (15 minutes)
10:15 am	**Session 6: Opportunities to Advance Progress in Public-Private Partnerships for Clinical Cancer Research** (1 hour, 5 minutes) *Co-Moderators:* *Roy Herbst, Yale University* *Richard L. Schilsky, University of Chicago* **Panelists:** Session 1: Roy Herbst and Richard L. Schilsky Session 2: Edith Perez and Heidi Smith Session 3: Gideon Blumenthal and Esther Krofah Session 4: Otis W. Brawley and Kristen Rosati Session 5: Neal Meropol and Lawrence Shulman
11:20 am	**Wrap-Up/Concluding Remarks** (10 minutes) *Planning Committee Co-Chairs:* *Roy Herbst, Yale University* *Richard L. Schilsky, University of Chicago*
11:30 am	**Adjourn**

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We are grateful for the support of our sponsors, which is crucial to the work of the Forum.

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Chief of Medical Oncology
Deputy Director for Clinical Affairs
Yale Cancer Center and Smilow Cancer Hospital
Assistant Dean for Translational Research
Yale School of Medicine

Richard L. Schilsky, MD, FACP, FSCT, FASCO *(Co-chair)*
Principal Investigator
ASCO TAPUR Study
Professor Emeritus
University of Chicago

Gideon Blumenthal, MD
Vice President, Regulatory Affairs - Oncology
Merck

Otis W. Brawley, MD, MACP, FRCP(L), FASCO, FACE
Bloomberg Distinguished Professor of Oncology and Epidemiology
Departments of Epidemiology and Oncology
Bloomberg School of Public Health
Associate Director
Community Outreach and Engagement
Sidney Kimmel Comprehensive Cancer Center
Johns Hopkins University

Chanita Hughes-Halbert, PhD
Vice Chair for Research and Professor
Department of Population and Public Health Sciences
Dr. Arthur and Priscilla Ulene Chair in Women's Cancer
Keck School of Medicine
Associate Director for Cancer Equity
Norris Comprehensive Cancer Center
University of Southern California

Samir N. Khleif, MD
Biomedical Scholar & Professor of Oncology
Director
Center for Immunology and Immunotherapy
Director
Jeannie and Tony Loop Laboratory for Immuno-Oncology
Lombardi Comprehensive Cancer Center
Georgetown University Medical Center
Member
Society for Immunotherapy of Cancer

Esther Krofah, MPP
Executive Director
FasterCures
Milken Institute

Scott M. Lippman, MD
Distinguished Professor
Associate Vice Chancellor for Cancer Research
UC San Diego Health
University of California, San Diego

Neal J. Meropol, MD
Vice President
Research Oncology
Flatiron Health

Edith A. Perez, MD
Chief Medical Officer, Bolt Biotherapeutics
Hematologist, Internist, and Oncologist
Mayo Clinic Jacksonville
Cancer Clinical Study Unit

Kristen Rosati, JD
Attorney
Partner
Coppersmith Brockelman PLC

Lawrence Shulman, MD, MACP, FASCO
Professor of Medicine
Associate Director, Special Projects
Director, Center for Global Cancer Medicine
Innovation Faculty
Penn Center for Cancer Care Innovation
Abramson Cancer Center
University of Pennsylvania

Heind (Heidi) Smith, MSHS
Vice President, Center of Operations and
Research Excellence (CORE)
US Clinical Development and Medical Affairs
Oncology
Novartis Pharmaceuticals

Robert A. Winn, MD
Director
Virginia Commonwealth University
Massey Cancer Center
Senior Associate Dean for Cancer Innovation
Professor of Pulmonary Disease and
Critical Care Medicine
Lipman Chair in Oncology
School of Medicine
Virginia Commonwealth University
School of Medicine
Vice President and President-Elect
Association of American Cancer Institutes

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Translational Science
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Friends of Cancer Research

Kirsten Bibbins-Domingo, PhD, MD, MAS
Editor in Chief
Journal of the American Medical Association (JAMA)
JAMA Network
Professor of Epidemiology & Biostatistics
Professor of Medicine
University of California, San Francisco

Barbara E. Bierer, MD
Professor of Medicine
Harvard Medical School (HMS)
Faculty Director
Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard
Member
HMS Center for Bioethics

Josh Bilenker, MD
Chief Executive Officer & Co-Founder
Treeline Biosciences

Charles D. Blanke, MD, FACP, FASCO
Chair
SWOG Cancer Research Network
Professor
OHSU Knight Cancer Institute
Oregon Health & Science University

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National Center for Advancing Translational Sciences
National Institutes of Health

John C. Byrd, MD, FACP
The Gordon and Helen Hughes Taylor Professor and Chair
Department of Internal Medicine
University of Cincinnati, College of Medicine
Chief Medical Officer
Beat AML LLC
Leukemia and Lymphoma Society

Matthew M. Cooney, MD
Vice President of Therapeutic Development, Oncology
Tempus

William L. Dahut, MD
Chief Scientific Officer
American Cancer Society, Inc.

Janet Dancey, MD, FRCPC
Director
Canadian Cancer Trials Group
Scientific Director
Canadian Cancer Clinical Trials Network
Edith and Carla Eisenhauer Chair in
Clinical Cancer Research
Professor
Queen's University, Kingston, ON, Canada

James H. Doroshow, MD
Director, Division of Cancer Treatment and
Diagnosis
Deputy Director for Clinical and
Translational Research
Head, Oxidative Signaling and
Molecular Therapeutics Group
National Cancer Institute
National Institutes of Health

S. Gail Eckhardt, MD, FASCO
Associate Dean of Experimental Therapeutics
Baylor College of Medicine
Associate Director of Translational Research
Dan L. Duncan Comprehensive Cancer Center

Elizabeth Garrett-Mayer, PhD, FSCT
Vice President of the Center for Research and
Analytics (CENTRA)
The American Society of Clinical Oncology

Julie Louise Gerberding, MD, MPH
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Foundation for the National Institutes of Health
Former Director
Centers for Disease Control and Prevention

Vassilis Golfinopoulos, MD, PhD
Headquarters Director
European Organisation for Research and
Treatment of Cancer

Prash Gopalakrishna, MD, MRCS
Medicine Team Leader
Pfizer Inc.

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Chief Executive Officer
Cholangiocarcinoma Foundation

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Breast Oncology Center
Institute Physician
Dana-Farber Cancer Institute
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Cancer Therapy Evaluation Program
Division of Cancer Treatment & Diagnosis
National Cancer Institute

Michael J. Morris, MD
Prostate Cancer Section Head
Clinical investigator
Professor
Memorial Sloan Kettering Cancer Center

Carolyn Muller, MD, FACOG
Professor and Chief
Division of Gynecology Oncology
Associate Director Clinical Research
University of New Mexico
Comprehensive Cancer Center

Gwen L. Nichols, MD
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The Leukemia & Lymphoma Society

Geoffrey Oxnard, MD
Vice President Clinical Development
Global Head Thoracic Cancer
Loxo@Lilly | Eli Lilly and Company

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Coppersmith Brockelman PLC

Eric Rubin, MD, PhD
Editor-in-Chief
New England Journal of Medicine
Adjunct Professor of Immunology and
Infectious Disease
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Experimental Immunology Branch
Deputy Director
National Cancer Institute
National Institutes of Health

Harpreet Singh, MD
Associate Director
Oncology in Older Adults and
Special Populations
Oncology Center of Excellence
United States Food and Drug Administration

Heind (Heidi) Smith, MSHS
Vice President, Center of Operations and
Research Excellence (CORE)
US Clinical Development and
Medical Affairs Oncology
Novartis Pharmaceuticals

Craig L. Tendler, MD
Vice President
Late Development, Diagnostics &
Global Medical Affairs
Oncology & Hematology
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Speaker, Panelist, Moderator, and Planning Committee Biosketches

Stacey J. Adam, PhD
Foundation for National Institutes of Health

Dr. Stacey Adam is an Associate Vice President at the FNIH, leading many public-private partnerships, such as Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV); the Biomarkers Consortium (Cancer and Metabolic Disorders Steering Committees) and their projects; Accelerating Medicines Partnerships (AMPs)-Common Metabolic Diseases, Heart Failure, and Parkinson's Disease, Partnership for Accelerating Cancer Therapies (PACT); and the Lung Master protocol (Lung-MAP) clinical trial.

Prior to FNIH, Dr. Adam was a Manager at Deloitte Consulting in the Federal Life Sciences and Healthcare Strategy practice where she supported many federal and non-profit client projects. Before Deloitte, Dr. Adam conducted her postdoctoral fellowship at Stanford University School of Medicine, where she was both an NIH and American Cancer Society supported fellow, and she earned her Ph.D. in Pharmacology with a Certificate in Mammalian Toxicology from Duke University.

Jeff Allen, PhD
Friends of Cancer Research

Jeff Allen, Ph.D. serves as the President and CEO of Friends of Cancer Research (Friends). For over 25 years, Friends has created unique scientific partnerships, accelerated policy change, and supported groundbreaking research to deliver new therapies to patients quickly and safely. As a key thought leader on issues related to the U.S. Food and Drug Administration, healthcare, and regulatory policy, he is regularly published in prestigious medical journals and policy publications and has contributed his expertise to the legislative process on multiple occasions. Recent Friends initiatives include the establishment of the Breakthrough Therapies designation, innovative research consortia to enhance biomarker development, and the launch of a unique cross-sector partnership to accelerate clinical trial conduct and rapidly assess if a patient's treatment is working. Jeff received his Ph.D. in cell and molecular biology from Georgetown University and holds a Bachelor of Science in Biology from Bowling Green State University.

Kirsten Bibbins-Domingo, PhD, MD, MAS
Journal of the American Medical Association (JAMA) and the JAMA Network

Kirsten Bibbins-Domingo, PhD, MD, MAS is 17th Editor-in-Chief of the Journal for the American Medical Association. She is the Lee Goldman, MD Professor of Medicine and Professor of Epidemiology and Biostatistics at the University of California, San Francisco. She previously served as the Chair of the Department of Epidemiology and Biostatistics and as the inaugural Vice Dean for Population Health and Health Equity in the UCSF School of Medicine. She co-founded the UCSF Center for Vulnerable Populations at Zuckerberg San Francisco General Hospital that focuses on actionable research to improve health equity and reduce health disparities.

Dr. Bibbins-Domingo is a general internist and cardiovascular epidemiologist whose scholarship includes observational epidemiology, pragmatic trials, and simulation modeling to examine clinical and public health approaches to prevention in the US and globally. She previously served on and led the US Preventive Services Task Force from 2010-2017. She has

received numerous honors, including induction into the American Society for Clinical Investigation, the National Academy of Medicine, and the American Academy of Arts and Sciences.

Barbara E. Bierer, MD
Trials Center of Brigham and Women's Hospital and Harvard University

Barbara E. Bierer, M.D., a hematologist-oncologist, is Professor of Medicine at Harvard Medical School and the Brigham and Women's Hospital (BWH). Dr. Bierer co-founded and now leads the Multi-Regional Clinical Trials Center of BWH and Harvard (MRCT Center, www.mrctcenter.org), a collaborative effort to improve standards for the planning and conduct of international clinical trials to harmonize policies for and approaches to clinical trial regulation. In 2017, the MRCT Center launched the non-profit organization, Vivli (www.vivli.org), a global clinical research data sharing platform. In addition, she is the Director of the Regulatory Foundations, Ethics, and the Law program at the Harvard Catalyst, the Harvard Clinical and Translational Science Award, working across the academic spectrum to enable the clinical trial enterprise from study planning through recruitment to data acquisition and dissemination. She is the Director and PI of SMART IRB (www.SMARTIRB.org), a national effort to align single site IRB review of multi-site trials. She serves as Faculty in the Center for Bioethics, Harvard Medical School, and as Affiliate Faculty in the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School. From 2003 – 2014, Dr. Bierer served as Senior Vice-President, Research at the Brigham and Women's Hospital (BWH). During her tenure, Dr. Bierer founded and served as Executive Sponsor of the Brigham Research Institute and the Brigham Innovation Hub (iHub), a focus for entrepreneurship and innovation in healthcare. She has authored approximately 300 publications.

In addition to her academic responsibilities, Dr. Bierer served or serves as Chair of the Secretary's Advisory Committee for Human Research Protections, Department of Health and Human Services (2008-2012); as a member of the National Academies of Sciences Committee on Science, Technology and the Law (2007-2016), and NASEM Forum on Drug Discovery, Development, and Translation (2023-); on the Executive Committee, Clinical Trials Transformation Initiative (2023-); on the Board of Directors of Public Responsibility in Medicine and Research (PRIM&R) (2011-2020), Management Sciences for Health (MSH) (2013-2022), Vivli (2017-), North Star Review Board (2020-), and Generation Patient (2023-). She chairs the Board of Trustees of the Edward P. Evans Foundation, a foundation supporting biomedical research, and is on the board of directors of Clinithink, a company that transforms unstructured clinical text into computable data for clinical trials and population health management.

Dr. Bierer received a B.S. from Yale University and an M.D. from Harvard Medical School.

Josh Bilenker, MD
Treeline Biosciences

Josh is the co-founder and CEO of Treeline Biosciences, a biotechnology company that he co-founded in 2021 with Jeff Engelman to discover new medicines for patients with cancer and other serious diseases. From 2013 to 2019, he was the co-founder and CEO of Loxo Oncology. Josh served as CEO of Loxo@Lilly from 2019 to 2021, after Eli Lilly acquired Loxo Oncology. From 2006 to 2013, Josh worked as a life sciences venture capital investor at Aisling Capital LLC. From 2004 to 2006, he served as a medical officer at the US Food and Drug Administration, in the Office of Oncology. Josh trained at the University of Pennsylvania in internal medicine and medical oncology, earning board certification in these specialties. He received his MD from The Johns Hopkins University School of Medicine and his AB degree in English from Princeton University.

Charles D. Blanke, MD, FACP, FASCO
Oregon Health & Science University

Charles D. Blanke, MD, FACP, FASCO, is a professor of medicine at the Knight Cancer Institute at Oregon Health & Science University (OHSU) and serves as chair of SWOG Cancer Research Network, an international group of nearly 6,000 physician-researchers that design and conduct cancer clinical trials. As part of the National Clinical Trials Network of the National Cancer Institute (NCI), SWOG is a worldwide leader in rigorous, large-scale cancer trials, with results leading to the approval of more than 14 FDA-approved drugs since its founding in 1956.

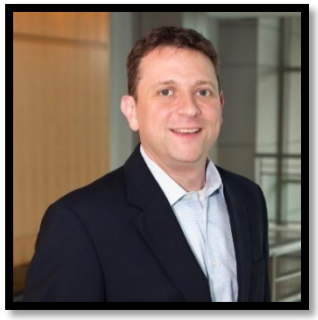
Dr. Blanke is committed to pathway-driven, patient-centered cancer research. Since taking over as chair of SWOG in 2013, he has advanced innovation, inclusion, and integrity by launching a major lung cancer precision medicine trial, creating a leadership program for young investigators, forging partnerships with VA medical centers nationwide, and making the group more accessible and accountable by instituting term limits for committee chairs and launching The Front Line, a weekly blog available at www.swog.org.

Dr. Blanke previously had a particular interest in investigational treatments that target the genetic and molecular abnormalities that cause cancer. He was instrumental in the development and approval of imatinib mesylate (Gleevec) for use in patients with locally advanced and metastatic gastrointestinal stromal tumors (GIST), and currently chairs the Gastrointestinal Stromal Tumor (GIST) Task Force for the NCI's Gastrointestinal Steering Committee. He has also significantly aided the development of chemobiotherapy use in patients with advanced colorectal cancers.

More recently, he is involved with policy and research issues related to medical-aid-in-dying (MAID), including the decision-making process, demographic descriptions of users, and drug development. He is a member of the Life's Door Hope Hub, an international collaborative group dedicated to engaging and inspiring people to live with hopefulness and meaning in the face of illness.

Before joining OHSU, Dr. Blanke was vice president of systemic therapy for the British Columbia Cancer Agency, professor and chief of medical oncology at the University of British Columbia, and head of medical oncology at Vancouver Hospital. Dr. Blanke serves on the American Society of Clinical Oncology (ASCO) Board of Directors, and is a fellow of ASCO and of the American College of Physicians. A SWOG member since 1999, Dr. Blanke served as subcommittee chair for colon cancer, then as chair of the group's gastrointestinal committee.

Dr. Blanke graduated first in his undergraduate class at Northwestern University, and then earned an MD with distinction from same institution. He completed his residency at Gundersen Medical Foundation, where he served as chief resident, and was a hematology/medical oncology fellow at Indiana University, where he served as chief fellow. He then served as faculty at Vanderbilt University, while heading its clinical trials research operation for a number of years.



Gideon Blumenthal, MD
Merck

Dr. Gideon Blumenthal is a hematologist oncologist who is currently Vice President, Oncology Clinical Development, Merck. He previously was Vice President of Global Oncology Regulatory affairs. Prior to joining Merck in 2020, Dr. Blumenthal spent over a decade at the US Food and Drug Administration Oncology office, taking on increasing leadership responsibilities. He initially served as a medical reviewer, then clinical team leader, followed by Acting Deputy Director in the Office of Hematology Oncology Products and Associate Director for Precision Oncology, and most recently as Deputy Center Director of the Oncology Center for Excellence. Dr. Blumenthal trained in internal medicine at the University of Maryland School of Medicine, followed by a hematology oncology fellowship at the National Cancer Institute. He was an attending physician in the NCI thoracic oncology clinic. He received numerous awards, including the 2018 American Society for Clinical Oncology Public Service Award. He has co-authored over 100 articles in the Oncology and Drug Development peer-reviewed literature and has authored numerous book chapters.

Otis W. Brawley, MD, MACP, FRCP(L), FASCO, FACE
Johns Hopkins University

Dr. Brawley is the Bloomberg Distinguished Professor of Oncology and Epidemiology at Johns Hopkins University. He is an authority on cancer screening and prevention and leads a broad interdisciplinary research effort focused on cancer health disparities at the Johns Hopkins School of Medicine, the Bloomberg School of Public Health, and the Sidney Kimmel Comprehensive Cancer Center. Brawley is a Fellow of the Royal College of Physicians (London), a Fellow of the American Society of Clinical Oncology, a Fellow of the American College of Epidemiology, and one of the few physicians to be named a Master of the American College of Physicians. He is an elected member of the National Academy of Medicine.

Dr. Brawley is a graduate of the University of Chicago Pritzker School of Medicine. He completed an internal medicine residency at Case-Western Reserve University and a fellowship in medical oncology at the National Cancer Institute. He is board certified in Internal medicine and medical oncology.

Penny Wung Burgoon, PhD
National Institutes of Health

Penny Burgoon, Ph.D., is the director of the Office of Policy, Communications and Education (OPCE), where she has focused the Office's efforts on strategic policy and communications, with an emphasis on educating others about and disseminating information on the value of effective translational science to benefit research. She joined NCATS in July 2014 as the chief of the Science Policy Branch, served as the acting director of OPCE in 2016, and was appointed permanent OPCE director in 2018.

Prior to her tenure at NCATS, she was the director of the Salivary Biology and Immunology Program for the National Institute of Dental and Craniofacial Research, where she managed a portfolio of research in salivary biology, salivary gland disorders and diseases. Burgoon joined NIH in 2004 as an American Association for the Advancement of Science AAAS Science Policy Fellow, providing program support for the first NIH-wide projects supported through the NIH Roadmap for Medical Research, now known as the NIH Common Fund. She then served as the senior assistant to the NIH principal deputy director from 2006 to 2010, coordinating activities across several NIH leadership committees, including the NIH Steering Committee, the NIH Advisory Committee to the Director, and Institute and Center Directors' meetings. Throughout her NIH career, she has been a member of numerous committees, serving all of NIH or its individual Institutes and Centers.

Burgoon received her bachelor's degree from Oberlin College, her master's degree from California State University, Northridge, and her doctorate in physiology from The Ohio State University.

John C. Byrd, MD, FACP
University of Cincinnati

John C. Byrd, MD, is an internationally known researcher and clinical specialist in leukemia and other hematologic malignancies. He currently is the Chair of the Department of Internal Medicine at the University of Cincinnati. He holds the Gordon and Helen Hughes Taylor Chair. Outside of his academic roles, Dr. Byrd is a principal and Chief Medical Officer of Beat AML, an LLC of the Leukemia and Lymphoma Society. The Beat AML study has brought together multiple industry, academic, and governmental stakeholders to move precision medicine in AML forward in the United States.

Dr. Byrd received his medical degree from the University of Arkansas for Medical Sciences. His education continued in internal medicine and hematology and oncology at Walter Reed Army Medical Center and Johns Hopkins University before moving to Columbus to join the faculty at Ohio State where he developed an internationally recognized blood cancer program and was the founding director of the Division of Hematology. He moved to the University of Cincinnati in 2021 as Chairman of Internal Medicine and also to contribute to building an NCI designated cancer center. Dr. Byrd runs a highly translational laboratory and early drug development program focused on CLL and new therapeutics in hematologic malignancies. He has been part of the successful development of multiple therapeutics in blood cancers, most notably the Bruton's Tyrosine kinase inhibitors (ibrutinib and acalabrutinib). He has over 650 publications, has been continuously funded by the NIH for over two decades, and has received multiple awards for his contribution to drug development in blood cancers. Dr. Byrd also currently chairs or serves as a member on multiple pharmaceutical company scientific advisory boards and has founded two companies stemming from his work.

Matthew M. Cooney, MD
Tempus

Dr. Matthew Cooney is a practicing hematologist and oncologist who previously was the multidisciplinary genitourinary team leader at University Hospitals Seidman Cancer Center. He has led and participated in dozens of phase I to III clinical studies.

Currently Dr. Cooney works at Tempus supporting the TIME Trials network which screens 1M+ patients daily using a combination of technology and nursing review to find potential subjects. Once an appropriate patient is identified, the TIME trial site is rapidly opened using a pre-approved clinical trials agreement, regulatory process, central IRB, and uniform contracting. This streamlined process has empowered the TIME Network to activate hundreds of trials in an average of 10 days. The TIME program has empowered patients to stay within their own community to participate in clinical research.

William L. Dahut, MD
American Cancer Society, Inc.

William L. Dahut, MD, is chief scientific officer of the American Cancer Society. In this role, he oversees the strategic direction of both intramural and extramural research for the largest nonprofit funder of cancer research. Dr. Dahut manages all pieces of ACS' Discovery Pillar, including surveillance and health equity science, population science, cancer screening guidelines, and extramural discovery science. He serves as the scientific voice of the organization, advises key discovery positions, and manages more than $400 million in research funding. Dr. Dahut guides efforts to enhance and focus the American Cancer Society's research program, concentrating priorities where they will be most effective and working with key partners and supporters to further progress.

At ACS, Dr. Dahut is leading the Discovery Pillar's contribution to the organization's mission to Improve the lives of people with cancer and their families, ensuring everyone has an opportunity to prevent, detect, treat, and survive cancer. That includes work such as: the launch of a new ACS Center for Diversity in Research Training, which seeks to increase efforts to recruit and nurture people of color within scientific and clinical training environments; a groundbreaking new cohort focused on Black women that will launch in pilot markets in 2023; and a new IMPACT initiative focusing on reducing disparities in prostate cancer mortality in Black men.

Across the board, Dr. Dahut puts words into action, leading a team of some of the world's most talented and highly cited researchers as they seek to "end cancer as we know it, for everyone." His team is working to fund exceptionally impactful cancer research, particularly in areas often overlooked by other organizations. They are increasing their focus on screening, early detection, prevention, and detection of cancer recurrence. They are looking into research on health care implementation; emphasizing the scientific importance of diversity, equity, and inclusion in every aspect of Discovery-funded research; and providing opportunities to accelerate bench-to-bedside work.

An internationally recognized physician-investigator, Dr. Dahut held leading roles at the National Cancer Institute before joining ACS. He was scientific director for clinical research at the NCI's Center for Cancer Research, head of the prostate cancer clinical research section, and NCI clinical director. Dr. Dahut has been laser-focused on helping cancer patients throughout his career, striking just the right balance between bench and bedside. Known as a tireless champion of clinical science, he has pioneered treatment regimens in prostate cancer and is a recognized expert in clinical trials and immunotherapy.

He received his MD from Georgetown University and completed clinical training in internal medicine at the National Naval Medical Center, followed by training in hematology and medical oncology at the Bethesda Naval Hospital and the Medicine Branch of the NCI.

Dr. Dahut sits on numerous boards and committees related to his work, has won distinguished honors and awards throughout his career, and is a prolifically published author, with nearly 250 pieces in peer-reviewed journals. He is chair-elect of the Department of Defense Prostate Cancer Research Program Integration Panel, has spoken to audiences across the country and around the world, and trained dozens of medical oncology fellows.

He is also professor of medicine at Uniformed Services University of the Health Sciences in Bethesda, Maryland, and continues to see patients in the prostate cancer clinic at Walter Reed National Medical Military Center.

Dr. Dahut lives in Bethesda, Maryland, with his family.

Janet E. Dancey, MD, FRCPC
Queen's University

Prior to becoming Director of the Canadian Cancer Trials Group on September 1, 2014, Dr. Dancey was Director, Translational Research – Clinical at Canadian Cancer Trials Group. She is also Scientific Director of the Canadian Cancer Clinical Trials Network (3CTN) and from 2008-2015 she was Director of the High Impact Clinical Trials Program at the Ontario Institute for Cancer Research. Prior to joining the Canadian Cancer Trials Group, Dr. Dancey was Senior Clinical Investigator in the Cancer Therapy Evaluation Program at the US National Cancer Institute and then Associate Chief of the Investigational Drug Branch. Dr. Dancey received her MD from the University of Ottawa and completed her residency training in internal medicine and medical oncology at the University of Toronto. In 1994-95, she was a research fellow with the Canadian Cancer Trials Group and continued her fellowship training at the Institut Gustave Roussy in France. Dr. Dancey has special expertise in new anti-cancer drug development, linking drug and biomarker development, and associated clinical trials methodology. She is also Professor in the Department of Oncology at Queen's University.

James H. Doroshow, MD
National Cancer Institute

Dr. James H. Doroshow has been the Director of Division of Cancer Treatment and Diagnosis, National Cancer Institute, since 2004, and Deputy Director for Clinical and Translational Research of the National Cancer Institute since 2011. From 1983 to 2004, Dr. Doroshow was the Chairman of the City of Hope Comprehensive Cancer Center's Department of Medical Oncology and Therapeutics Research. From the time of his first research grant in 1980, Dr. Doroshow was continuously funded by NCI until he moved to the NIH in 2004. He is the author of over 400 full-length publications in the areas of reactive oxygen metabolism and oxidant signaling, anticancer pharmacology, and novel therapeutic approaches to solid tumors. Dr. Doroshow served from 1987-1992 as a member and then Chair of the NIH Experimental Therapeutics II Study Section; from1995-2001 as a member of the Subspecialty Board on Medical Oncology of the American Board of Internal Medicine; from 1999-2000 as Chair of NCI's Scientific Review Group A-Cancer Centers; from 2004-2007 as a member of the FDA's Oncologic Drugs Advisory Committee; and in 2013 as Co-Chair of the NIH Clinical Trials Working group. He is currently a member of the Institute of Medicine's Forum on Drug Discovery, Development, and Translation; an Associate Editor of the 5th Edition of Abeloff's Clinical Oncology (2014); and the Oncology Editor of the 25th Edition of the Cecil Textbook of Medicine (2015). Dr. Doroshow received his bachelor's degree, magna cum laude, from Harvard College in 1969 and his medical degree from Harvard Medical School in 1973. After completing an internship and residency in Internal Medicine at the Massachusetts General Hospital in Boston, he spent three years (1975-78) performing his fellowship in Medical Oncology on the Medicine and Clinical Pharmacology Branches of the NCI.

S. Gail Eckhardt, MD, FASCO
Baylor College of Medicine

S. Gail Eckhardt is Associate Dean for Experimental Therapeutics at Baylor College of Medicine and Associate Director of Translational Research at the Dan L. Duncan Comprehensive Cancer Center. Dr. Eckhardt has served on numerous committees and study sections, including the ASCO Molecular Oncology Task Force, the ASCO Board of Directors, the FDA Oncology Drugs Advisory Committee, and the National Cancer Institute (NCI) Cancer Centers Study Section. She is a member of the NCI Investigational Drug Steering Committee and serves on 11 external advisory boards of NCI-designated cancer centers. She

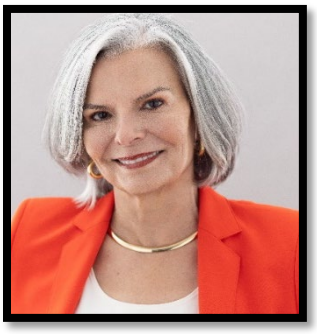
was a lead mentor in ASCO's Leadership Development Program, is a past member of the Board of Directors of the Association of American Cancer Institutes (AACI) and Chair of the Cancer Prevention and Research Institute of Texas' Clinical Trials Advisory Committee. Dr. Eckhardt was awarded ASCO's Women Who Conquer Cancer Mentorship Award in 2022 and is currently a member of the National Academies of Sciences, Engineering, and Medicine's National Cancer Policy Forum.

Dr. Eckhardt has been Principal Investigator on grants involving early clinical trials and colorectal cancer research, has conducted numerous early phase clinical trials, and has published over 200 manuscripts. Her area of interest is in the preclinical and early clinical development of combinations of molecularly targeted compounds. Dr. Eckhardt earned her undergraduate degree in chemistry from Stephen F. Austin State University and her medical degree from the University of Texas Medical Branch in Galveston. She conducted her internship and residency in Internal Medicine at the University of Virginia Medical School, followed by a post-doctoral research fellowship in Experimental and Molecular Medicine at Scripps Research Institute in La Jolla, California, and a fellowship in Medical Oncology at the University of California San Diego.

Elizabeth Garrett-Mayer, PhD, FSCT
The American Society of Clinical Oncology

Dr. Garrett-Mayer joined ASCO in 2017 as CENTRA's Division Director for Biostatistics and Research Data Governance and became CENTRA's first Vice President in 2022. CENTRA leads ASCO's research efforts, including the TAPUR Study, the CDK Study, and research projects aimed cancer care and improving representation in clinical trials. Prior to joining ASCO, she served on the faculty in the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins in the Department of Oncology, and then joined the faculty of the Medical University of South Carolina (MUSC) and established the Biostatistics Shared Resource at the Hollings Cancer Center (HCC).

She earned her bachelor's degree from Bowdoin College and a PhD in Biostatistics from Johns Hopkins Bloomberg School of Public Health. During her time at Johns Hopkins and MUSC, she taught courses in biostatistics and public health science, and mentored pre- and post-doctoral students. Her publication record includes more than 300 peer-reviewed publications, primarily in early phase clinical trial design methods and clinical cancer research. She has been a member of numerous NIH grant review committees, NCI task forces and steering groups, Data Safety Monitoring Boards for NIH-supported clinical trials, serves on the editorial board of three peer-reviewed journals and was faculty on the ASCO/AACR Methods in Clinical Cancer Research Workshop for over a decade.



Julie Louise Gerberding, MD, MPH
Foundation for the National Institutes of Health

Dr. Julie Louise Gerberding is the President and CEO of the Foundation for the National Institutes of Health (FNIH), a non-profit organization that builds public-private research partnerships to support the mission of the NIH. She co-chairs the CSIS Bipartisan Alliance on Global Health Security and is a member of the Commonwealth Fund Commission on a National Public Health System. Previously, she served as President of Merck Vaccines and as Executive Vice President and the Chief Patient Officer at Merck & Co., Inc. From 2003-2009, Dr. Gerberding led the U.S. Centers for Disease Control and Prevention (CDC). She serves on the boards of HilleVax, Mayo Clinic, National Health Council, and Case Western Reserve University. Dr. Gerberding is a member of the National Academy of Medicine and the adjunct faculties of the University of California, San Francisco, and Case Western Reserve University.

Vassilis Golfinopoulos, MD, PhD
European Organisation for Research and Treatment of Cancer (EORTC)

Dr. Vassilis Golfinopoulos serves as the EORTC Headquarters Director, overseeing the operation of the clinical research infrastructure of EORTC. His tasks include the development and implementation of the EORTC's scientific strategy by coordinating the scientific, operational, and project management activities of EORTC Headquarters.

Prash Gopalakrishna, MD, MRCS
Pfizer Inc.

Prash is currently Vice President and Medicine team lead at Pfizer, where he oversees end-to-end strategic development and delivery of assigned assets in Pfizer's portfolio that are being developed for Breast cancer.

Prash has over 15 years of experience in global oncology drug development, with roles of increasing leadership and responsibilities in large biopharma sectors. Prash is a seasoned surgeon-scientist and senior executive with wide-ranging experiences in biopharmaceutical research and development, medical affairs and digital medicine. Prash is a proven global drug developer, whose leadership and oversight have led to the development of multiple medicines in oncology & haematology indications, while setting drug development precedents along the way.

Among Prash's many accomplishments are: receiving global approvals of Erlotinib for NSCLC, Eribulin for Breast Cancer, Ruxolitinib for Myelofibrosis, and Tasigna for CML (including the introduction of Treatment Free Remission concept for CML), and global launches for Ribociclib (BC), Alpelisib (BC) and Crizalizunmab (Sickle cell disease).

Aida Habtezion, MD, MSc, FRCPC, AGAF
Pfizer Inc.

As Chief Medical Officer of Pfizer, Aida Habtezion leads Pfizer's Worldwide Medical & Safety organization responsible for ensuring that patients, physicians, and regulatory agencies are provided with information on the safe and appropriate use of Pfizer medications. Her organization is responsible for monitoring the benefit risk profile and safety of Pfizer's portfolio of products from the first person that receives an investigational medicine or vaccine to the millions of patients that rely on these marketed therapies every day. She also leads Pfizer's Institute of Translational Equitable Medicine (ITEM), an initiative spanning research, development, and medical activities to close gaps in health disparities. The Institute leverages science, data, and translational expertise to integrate equity across Pfizer's end-to-end development pipeline.

Prior to joining Pfizer, Dr. Habtezion was an endowed and tenured Professor of Medicine, a practicing physician and scientist at Stanford University's School of Medicine, Division of Gastroenterology and Hepatology. She is board certified in Gastroenterology in both Canada and the United States. She led a large translation research lab funded by multiple NIH, DOD, and foundation grants focused on understanding disease mechanisms and identifying potential immune-based therapeutic targets for pancreatic and intestinal inflammatory diseases and authored over a hundred high impact publications in top peer-reviewed journals. She also served as an Associate Dean for Academic Affairs, a faculty member in Stanford's Immunology Ph.D. program, Neuroscience Institute, Cancer Institute, Maternal & Child Health Research Institute, interdisciplinary biosciences institute Bio-X, and a faculty fellow at Stanford's ChEM-H (Chemistry, Engineering

& Medicine for Human Health). Dr. Habtezion served in several national and international study sections, including six years in NIH study section, the American Gastroenterological Association (AGA) Institute Research Awards, and the AGA Research Policy Committee. Dr. Habtezion is the recipient of the Robert Wood Johnson Harold Amos Medical Faculty Development Award, Gastroenterology & Hepatology Teaching Award, the Immunology Faculty Mentor of the Year, and the Kenneth Rainin Foundation Synergy Award. She is a Fellow of the American Gastroenterological Association, an Allen Distinguished Investigator, an elected member of the American Society for Clinical Investigation (ASCI) and the Association of American Physicians (AAP). She currently serves in the New York Academy of Sciences Board of Governors, the Executive Board for the International Science Reserve, the Connecticut Business & Industry Association Board of Directors, the Pfizer Foundation Board, the PhRMA Foundation Board of Directors, and is the past president of the American Pancreas Association (APA).

Dr. Habtezion obtained her Bachelor of Science in Chemistry from the University of Alberta and Master of Science in Nutritional Sciences from the University of Guelph. She completed her medical degree from McMaster University. Dr. Habtezion completed her Internal Medicine residency from the University of Western Ontario and Gastroenterology & Hepatology clinical fellowship from the University of Toronto in Canada. Following her clinical fellowship training, she obtained postdoctoral research training in Immunology at Stanford University.

Roy S. Herbst, MD, PhD *(Co-Chair)*
Smilow Cancer Hospital, Yale Comprehensive Cancer Center, and Yale School of Medicine

Roy S. Herbst, MD, PhD is Deputy Director for Yale Cancer Center and Chief of Medical Oncology for Yale Cancer Center and Smilow Cancer Hospital. He is Ensign Professor of Medicine at Yale School of Medicine.

Dr. Herbst has worked over several decades as a pioneer of personalized medicine and immunotherapy to identify biomarkers and bring novel targeted treatments and immunotherapies to patients, serving as principal investigator for numerous clinical trials testing these agents in advanced stage lung cancers. This work led to the approval of several therapies (such as gefitinib, cetuximab, bevacizumab, axitinib, atezolizumab, and pembrolizumab), which have revolutionized the field and greatly enhanced patient survival. His leadership in targeted therapeutics resulted in a 2020 ASCO plenary talk and publication of results of the third-generation EGFR-inhibitor osimertinib for the treatment of resected EGFR-mutant NSCLC in the New England Journal of Medicine. IN 2023 her presented the positive overall survival results from this trial at the ASCO plenary session published with his coauthors in the New England Journal. He and his Yale colleagues were among the first to describe the PD-1/PD-L1 adaptive immune response in early phase trials and to offer trials of PD-L1 inhibitors atezolizumab and pembrolizumab to lung cancer patients. In 2015 and again in 2020, his team at Yale was awarded a Lung Cancer SPORE (P50 grant) by the NCI, which has identified new immunotherapies and mechanisms of sensitivity and resistance to EGFR targeted therapies.

His work on "umbrella" trials has galvanized the field of targeted therapy and cancer drug approvals at the FDA. Nationally, he works closely with public-private partnerships to develop large master protocol clinical studies, such as Lung-MAP for which he served as the founding PI and Chair from 2013-2022 and now remains as chair emeritus. . He testified on the subject of modernizing clinical trials during the 21st Century Cures hearing before the US House of Representatives Subcommittee on Health and has served as a prominent figure in the public policy arena, for nine years having served as a member of the National Academy of Medicine's Cancer Policy Forum, for which he organized several meetings focused on policy issues in personalized medicine and tobacco control.

Dr. Herbst is a highly respected clinician- scientist who has been a champion of translational medicine for decades, recently authoring a high-profile review of the 20-year progress in lung cancer. He has authored or co-authored more than 400 publications, including peer-reviewed journal articles, abstracts, and book chapters. His work has appeared in many prominent journals, such as the Journal of Clinical Oncology, Clinical Cancer Research, Lancet, and the New England Journal of Medicine. Work published in Nature was awarded the 2015 Herbert Pardes Clinical Research Excellence Award by the Clinical Research Forum.

He is a Fellow of the American Society of Clinical Oncology and a member of the American Association of Cancer Research (AACR), where he served as an elected member of its board of directors and chairs the Scientific Policy and Government Affairs Committee. He has been a major proponent of efforts to promote tobacco control and regulation (including e-cigarettes), authoring multiple policy statements and leading frequent Capitol Hill briefings. In 2019 he was elected to the International Association for the Study of Lung Cancer (IASLC) board of directors. He is a fellow of the American College of Physicians and an elected member of the Association of American Physicians. He is vice chair of the Southwestern Oncology Group's (SWOG) Lung Committee.

For his lifetime achievement in scientific contributions to thoracic cancer research, Dr. Herbst was awarded the 2016 Paul A. Bunn, Jr. Scientific Award by the IASLC at their 17th World Conference on Lung Cancer in Vienna, Austria. A team of Yale Cancer Center investigators led by Roy S. Herbst, MD, PhD, was awarded the 2018 Team Science Award from the Association for Clinical and Translational Science (ACTS) for its pioneering work in advancing our understanding of Immunotherapy. In 2020, Dr. Herbst was awarded the AACR Distinguished Public Service Award for Exceptional Leadership in Cancer Science Policy.

For his lifetime achievement in scientific contributions to thoracic cancer research, Dr. Herbst was awarded the 2016 Paul A. Bunn, Jr. Scientific Award by the IASLC at their 17th World Conference on Lung Cancer in Vienna, Austria. A team of Yale Cancer Center investigators led by Roy S. Herbst, MD, PhD, was awarded the 2018 Team Science Award from the Association for Clinical and Translational Science (ACTS) for its pioneering work in advancing our understanding of Immunotherapy. In 2020, Dr. Herbst was awarded the AACR Distinguished Public Service Award for Exceptional Leadership in Cancer Science Policy.

Tony Hickson, BSc, MBA, CLP, RTTP
Cancer Research UK, Cancer Research Horizons

Tony Hickson is the Chief Business Officer for Cancer Research UK and Cancer Research Horizons. He leads the Commercial Partnerships team responsible for the commercialisation of IP from CRUK funded projects, new start-up creation, licences and corporate alliances. Prior to this Tony was the Managing Director of Imperial Innovations Ltd, responsible for intellectual property sourcing, licensing and spin-out creation for technologies arising from Imperial College London. During this tenure, Tony also spent 5 years as an executive director on the board of Touchstone Innovations PLC, an investment company listed on the London Stock exchange investing in deep science projects from UK universities. Prior to joining Imperial Innovations/Touchstone, Tony acquired 15 years of commercial and business development experience in bioscience companies including Wellcome Group R&D, Murex Biotech, Abbott Laboratories and Kalibrant Limited. Tony has sat on the IP boards of two European Institutes of Technology (Healthcare and Climate Change), sat on the BBSRC industry advisory panel for 2 years, was a board director of PraxisAurill, a board advisor to Cambridge Enterprise and is a member of the Francis Crick Institute's Translational Advisory Group. He has a diploma in company direction from the Institute of Directors and is a Certified Licensing Professional.

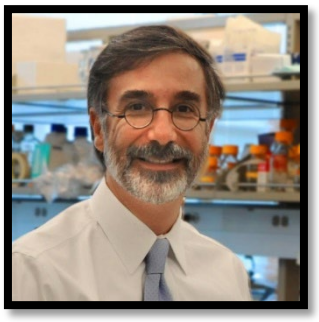
Chanita Hughes-Halbert, PhD
University of Southern California

The goal of Dr. Hughes-Halbert's research program is to improve the precision of multilevel strategies for achieving health equity by identifying diverse determinants of minority health and cancer health disparities and by translating this information into sustainable interventions in clinic and community-based settings to improve cancer outcomes and chronic disease management in disparity populations in local and regional geographic areas. Dr. Hughes-Halbert is a nationally recognized expert in cancer prevention and control among diverse populations and her research is supported by numerous grants from the National Cancer Institute, the National Institutes on Minority Health and Health Disparities, and the Veteran's Affairs Medicine Center. Previously, she was a member of the Board of Scientific

Advisors at the National Cancer Institute and the National Human Genome Research Institute Advisory Council. Dr. Hughes-Halbert is a past recipient of the AACR Distinguished Lecture in Cancer Health Disparities Award and is a member of the National Academy of Medicine.

Melissa Johnson, MD
Sarah Cannon Research Institute

Johnson is a medical oncologist whose research focus is new drug development for patients with lung cancer. In 2021, Dr. Johnson assumed the role of director of the Lung Cancer Research Program for Sarah Cannon Research Institute, where she supervises the lung cancer clinical trial portfolio across the Sarah Cannon network. Johnson is the co-leader of the Immune Effector Cell Therapies program, and has directed the development of the Solid Tumor Cellular Therapy program in the Drug Development Unit in Nashville. Prior to joining Sarah Cannon, Johnson was an Associate Professor at Northwestern University and Feinberg School of Medicine She earned her medical degree from the University of Pennsylvania. After completing residency in internal medicine at New York Hospital/Weill Cornell Medical Center, she did her fellowship training at Memorial Sloan Kettering Cancer Center where she served one year as chief fellow. She is board certified in internal medicine and medical oncology.



Samir N. Khleif, MD
Georgetown University Medical Center

Dr. Samir N. Khleif is currently a Biomedical Scholar and a professor in Medicine and Oncology at Georgetown University Medical School and the Director of the Center for Immunology and Immunotherapy and the Loop Immuno-Oncology Laboratory. Dr. Khleif is a pioneer, a leading basic and clinical scientist, and a Key Opinion Leader in the field of immunotherapy.

Dr. Khleif was an NIH Scientist for more than 20 years and served as Chief of the Cancer Vaccine Section at the National Cancer Institute pioneering many of the early concepts of immunotherapy. He led the development of conduct of the earliest trials in neoantigen vaccines and the understanding of the mechanism of resistance to immunotherapy and immune combination. He previously served as the founding Director of the Georgia Cancer Center at Augusta University - the Georgia University System's cancer center. He also served as the Special Assistant to the Commissioner of the Food and Drug Administration (FDA) where he led the FDA's Transformational Critical Path Initiative for Oncology, a project that reformed the process of cancer drug development in the US.

Dr. Khleif was detailed by the US government to serve as the founder and CEO/Director General of the King Hussein Cancer Center (KHCC) in Jordan, the premier cancer center in the Middle East. And then, at the request of the King of Jordan and the US government, he developed the King Hussein Institute of Biotechnology and Cancer (KHIBC) and helped Jordan reform health care and higher education.

He is an international leader and KOL on global health where he serves in an advisory capacity on both governmental and non-governmental expert bodies. He also sits on many national and international committees that are driving global oncology and the immune-oncology field forward.

Dr. Khleif has been the recipient of many national and international awards; amongst others, the National Cancer Institute's Director Golden Star Award, the National Institutes of Health Award for Merit, the Commendation Medal of the US Public Health Service, the Georgia State Distinguished Cancer Scientists and Clinicians Award and the Lifetime Achievement Award of the Jordan Medical Association for one of the most influential physicians contributing to advancing health care in Jordan in 50 years.

He is the author of numerous peer review articles, the editor of 3 books, the author of many and the holder of more than 100 national and international patents and patent applications. His team currently works on exploring T cell plasticity and signaling engineering, mechanism of resistance of immunotherapy and strategies to reverse resistance, and development of novel immune-therapeutic approaches.

Dr. Khleif earned his medical degree from the University of Jordan, completed a residency in internal medicine from the Medical College of Ohio, and a fellowship in medical oncology from the National Cancer Institute.

Esther Krofah, MPP
Milken Institute and FasterCures

Esther Krofah is the executive vice president of Milken Institute Health, leading FasterCures, Public Health, the Future of Aging, and Feeding Change. She has extensive experience managing efforts to unite diverse stakeholders to solve critical issues and achieve shared goals that improve patients' lives. Most recently, Krofah was the director of public policy at GlaxoSmithKline (GSK), where she led engagement with the US Department of Health and Human Services (HHS) and relevant Executive Branch agencies on broad healthcare policy issues. Before GSK, Krofah was a deputy director of HHS' Office of Health Reform. She also served as program director at the National Governors Association healthcare division and worked in consulting at Deloitte Consulting LLP. Krofah received a B.A. from Duke University and a Master's of Public Policy from the Harvard University John F. Kennedy School of Government.

Stacie C. Lindsey, BS
Cholangiocarcinoma Foundation

Stacie Lindsey is the Founder and Chief Executive Officer of the Cholangiocarcinoma Foundation (CCF). Established in 2006, CCF's mission is to find a cure and improve the quality of life for those affected by cholangiocarcinoma (bile duct cancer) through advocacy, education, collaboration, and research.

Stacie regularly engages with patients, caregivers, and advocates, members of the scientific, medical, and academic communities, policymakers and regulators, and industry and corporate entities to advance and increase scientific research to benefit patients with cholangiocarcinoma.

She is a frequent presenter at scientific meetings and medical conferences, including AASLD, GI ASCO, FDA, NIH, FASEB, ENS-CCA, AHPBA, AASLD, WAILD and scores of others. Foundation supported research outcomes have been published in numerous scientific publications, including Nature, Journal of Clinical Oncology, Hepatology, and Gastroenterology Oncology, among others.
She and the Cholangiocarcinoma Foundation were the first cancer advocacy organization to participate in the Food and Drug Administration's Project Livin' Label educational initiative through the video Episode 2 – Pemigatinib: The Backstory.

She serves on the Steering Committees of the Global Cholangiocarcinoma Alliance, the Cholangiocarcinoma Summit Meeting, and the Cancer Precision Medicine Commons. She is a Founding member of the GI Cancers Alliance, the Asia Pacific Cholangiocarcinoma Conference, and the International Cholangiocarcinoma Research Network, a global consortium of researchers from 23 countries. She is the Lead Patient Advocate on the Mayo Clinic Hepatobiliary SPORE.

Scott M. Lippman, MD
University of California, San Diego

Dr. Lippman is a distinguished professor of medicine and associate vice chancellor for cancer research at UC San Diego (UCSD) School of Medicine; and director of the Pre-Cancer Genome Atlas (PCGA). He holds an adjunct professorship at the Salk Institute and MD Anderson Cancer Center, and was immediate past Director of the UCSD NCI Comprehensive Moores Cancer Center and Chair, UC Cancer Consortium.

Dr. Lippman is an NIH R01-funded physician-scientist, and elected member of the prestigious Association of American Physicians (AAP). He has authored more than 300 publications in high-impact journals, including The New England Journal of Medicine, the Journal of the American Medical Association, Proceedings of the National Academy of Sciences, and The Lancet, and chapters in major medical textbooks. He has been recognized in major "Top Doctor" listing including U.S. News & World Report, and received numerous awards, including from the American Cancer Society (ACS), American Society of Clinical Oncology (ASCO), Stand up to Cancer (SU2C), and the American Association for Cancer Research (AACR). Dr. Lippman was also a member of the Board of Directors for the AACR, the Association of American Cancer Institutes, and the National Comprehensive Cancer Network, and has served as a standing member on the FDA Oncologic Drugs Advisory Committee (ODAC).

Before joining UCSD in 2012, Dr. Lippman was on faculty at MD Anderson Cancer Center for 24 years, including as a tenured professor, where he held three endowed positions, and was distinguished chair of two departments, most recently the Department of Thoracic/Head and Neck Medical Oncology. He completed internship and residency training in internal medicine at the Johns Hopkins Hospital and Harbor-UCLA Medical Center, and fellowships in hematology and medical oncology at Stanford University and the University of Arizona. He received his medical degree from Johns Hopkins University School of Medicine, and is triple-board certified in internal medicine, hematology, and medical oncology.

Erica L. Mayer, MD, MPH, FASCO
Dana-Farber Cancer Institute

Erica L. Mayer, MD, MPH, is an Institute Physician and breast cancer medical oncologist in the Susan F. Smith Center for Women's Cancers at the Dana-Farber Cancer Institute, as well as an Associate Professor in Medicine at Harvard Medical School. She is the Director of Clinical Research for the Dana-Farber Breast Oncology Center.

Dr. Mayer received her medical degree from Harvard Medical School in 2000. She completed a residency in Internal Medicine at Brigham and Women's Hospital, and a fellowship in Hematology/Oncology at Dana-Farber Cancer Institute/ Partners CancerCare. She obtained a Master's in Public Health from the Harvard School of Public Health. She was awarded the 2023 Canellos Award for Excellence in Clinical Investigation and Patient Care and is a Boston Magazine "Top Doctor."

Dr. Mayer's research focuses on the role of novel therapies in the treatment of breast cancer. She has been published in numerous peer-reviewed publications including Nature, Lancet Oncology, Journal of Clinical Oncology, and Annals of Oncology. She is the former Associate Director of the Dana-Farber Partners CancerCare Hematology/Oncology Fellowship Program, President of the Dana-Farber Medical Staff, and Co-Chair of the Dana-Farber Cancer Institute Clinical Faculty Council. Dr. Mayer is an active member of ASCO, ALLIANCE, as well as the Translational Breast Cancer Research Consortium. She is a graduate of the ASCO Leadership Development Program and has chaired multiple other ASCO committees including Cancer Communications Committee and breast cancer tracks for Cancer Education Committee and the Scientific Program.

Deven McGraw, JD, MPH, LLM
Invitae/Ciitizen

Deven McGraw is the lead for Data Stewardship and Data Sharing at Invitae, a clinical genetic medicine company. Previously, she co-founded and served as Chief Regulatory Officer for Ciitizen, a platform for patients to gather and manage their health information, prior to its acquisition by Invitae in 2021. From 2015-2017, she directed U.S. health privacy and security as Deputy Director, Health Information Privacy at the HHS Office for Civil Rights and Chief Privacy Officer (Acting) of the Office of the National Coordinator for Health IT. She was recently appointed by GAO to a three-year term on the Health Information Technology Advisory Committee. Widely recognized for her expertise in health privacy, she directed the Health Privacy Project at the Center for Democracy & Technology for six years, testifying before Congress on health privacy issues on multiple occasions and leading the privacy and security policy work for the HITECH Health IT Policy Committee. She also is currently serving on the Data and Surveillance Workgroup of the CDC's Advisory Committee to the Director on CDC's Data Modernization and on the board of Manifest MedEx, the largest health information exchange in California. She previously was the Chief Operating Officer of the National Partnership for Women and Families and, before joining federal government service, advised health industry clients on HIPAA compliance and data governance while a partner at Manatt, Phelps & Phillips, LLP. Deven graduated magna cum laude from Georgetown University Law Center and has a Master of Public Health from Johns Hopkins University.

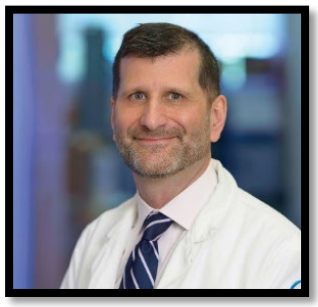
Neal J. Meropol, MD
Flatiron Health

Neal J. Meropol, MD is a medical oncologist, clinical investigator and outcomes researcher who serves as Vice President of Research Oncology at Flatiron Health. In this role, he provides scientific and clinical leadership in leveraging Flatiron's technology platforms to close the gap between research and clinical care. Dr. Meropol is currently co-chair of the NCI Streamlining Clinical Trials Working Group, and is immediate past chair of the NCI Clinical Trials and Translational Research Advisory Committee. Dr. Meropol completed a four-year term as an elected member of the American Society of Clinical Oncology (ASCO) Board of Directors, and served as chair of the AACR/ASCO Methods in Cancer Clinical Research Workshop, and ASCO Leadership Development Program. Dr. Meropol's research contributions span drug development and health services research, including evaluation of new agents, predictors of response and outcome, assessment of the economic impact of care, and development of tools to overcome barriers to clinical trial participation.

Meg Mooney, MD
National Cancer Institute

Meg Mooney, MD received her medical degree from the University of Chicago Pritzker School of Medicine in Chicago and her general surgical training at the Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire. She completed her Surgical Oncology fellowship training at the Roswell Park Cancer Institute in Buffalo, New York, and also holds a Master of Science degree in Management from the Massachusetts Institute of Technology in Cambridge, Massachusetts.

Dr. Mooney joined NCI in 2002 as Head of Gastrointestinal and Neuroendocrine Cancer Therapeutics in the Clinical Investigations Branch in the Cancer Therapy Evaluation Program (CTEP). She was appointed Chief of the branch in May 2009 with responsibility for the NCI direction of the National Clinical Trials Network Program. In April 2020, she became the Associate Director of CTEP, with oversight and coordination responsibilities for the programmatic, financial, and administrative functions for the entire CTEP program, which covers a broad, multidisciplinary, clinical research effort to coordinate nationwide phase 1-3 clinical trials programs testing new treatment approaches for cancer.



Michael J. Morris, MD
Memorial Sloan Kettering Cancer Center

Dr. Morris is a prostate cancer specialist, clinical investigator, professor, and the Prostate Cancer Section Head at Memorial Sloan Kettering Cancer Center. He earned his medical degree from the Mount Sinai School of Medicine in New York and performed his internship and residency in Internal Medicine at Columbia Presbyterian Medical Center. He then completed his medical oncology fellowship at Memorial Sloan Kettering Cancer Center.

Dr. Morris has led numerous clinical trials but has a particular research focus on targeted therapy for prostate cancer, especially those that bridge the fields of Medical Oncology and Nuclear Medicine. In the field of therapeutics, he has focused on tumor and bone-directed radiopharmaceuticals for prostate cancer. He was part of the leadership team that developed Lu-177 PSMA-617, which is now FDA approved for men with advanced prostate cancer. He has a research focus interest in developing novel imaging technologies for metastatic prostate cancer and in credentialing imaging biomarkers. He has been a co-developer of the Prostate Cancer Working Group 2 and 3 Consensus Criteria, and prostate-specific imaging technologies such as PSMA-directed PET imaging.

In addition to these responsibilities at MSK, he has long had an interest in novel methods of implementing prostate cancer clinical trials, and utilizing telehealth to reduce barriers to expertise, clinical care, and investigational studies. He now co-Directs the NCI Clinical Trials Innovation Unit, a new multiagency vehicle designed to expedite the deployment of innovation in clinical trials, and serves as an advisor to the NCI Director.

Carolyn Muller, MD, FACOG
University of New Mexico Comprehensive Cancer Center

Dr. Muller is Professor and Chief of Gynecologic Oncology at the University of New Mexico and Associate Director for Clinical Research at the UNM Comprehensive Cancer Center. She is a trained physician-scientist who is very active clinically and in collaborative research with a focus on clinical-translational trials in ovarian and endometrial cancer. Dr. Muller's research focus is in the surgical and medical management of ovarian cancer and has special expertise in clinical trials. Dr. Muller is nationally recognized for her scientific contributions in Gynecologic Oncology. She serves as a scientific reviewer for several National Institute of

Health and Department of Defense committees. She has nearly thirty years of Gynecologic Oncology experience and continues to practice comprehensive contemporary management of all issues facing women with a gynecologic cancer. She cares for women from many diverse economic and cultural backgrounds in New Mexico and is interested in overcoming such barriers to clinical trials in her patient population.

Gwen L. Nichols, MD
The Leukemia & Lymphoma Society

As LLS's chief medical officer, Gwen Nichols, M.D., plays a critical role in advancing cures through a unique combination of clinical, academic and pharmaceutical experience. She oversees LLS's scientific research portfolio, education, patient services, policy and advocacy initiatives. Most recently, Dr. Nichols was oncology site head of the Roche Translational Clinical Research Center. Prior to joining Roche in 2007, Dr. Nichols was at Columbia University for more than ten years, where she served as the director of the Hematologic Malignancies Program. While at Columbia University, Dr. Nichols maintained an active clinical practice and received the prestigious honors of "Physician of the Year" from Columbia University and the "Humanism in Medicine Award" from the American Association of Medical Colleges.

Geoffrey Oxnard, MD
Loxo Oncology, Eli Lilly

Dr. Geoff Oxnard is VP Clinical Development, Global Head Thoracic Cancers, at Loxo @ Lilly Oncology. Geoff was previously SVP, Head of Clinical Development at Foundation Medicine, and prior to this was Associate Professor at Dana-Farber Cancer Institute and Harvard Medical School. He has had an impactful research career studying precision therapies, treatment resistance, and novel diagnostics with >150 publications. He continues to see lung cancer patients part time at Boston Medical Center.

Richard Pazdur, MD
United States Food and Drug Administration

Richard Pazdur, M.D., is director of FDA's Oncology Center of Excellence (OCE), which leverages the combined skills of FDA's regulatory scientists and reviewers with expertise in drugs, biologics, and devices to expedite the development of novel cancer products. In this role, Dr. Pazdur leads the effort to develop and execute an integrated regulatory approach to enhance cross-center coordination of oncology product clinical review.

Prior to joining FDA in 1999, Dr. Pazdur was professor of medicine at The University of Texas M.D. Anderson Cancer Center. From 1982 to 1988, he served on the faculty of Wayne State University. He received his bachelor's degree from Northwestern University, his M.D. from Loyola Stritch School of Medicine, and completed clinical training at Rush-Presbyterian St. Luke's Medical Center and University of Chicago Hospitals and Clinics.

Dr. Pazdur has published more than 800 articles, book chapters, and abstracts, and two medical oncology textbooks. He was recognized in Fortune's 2015 list of "50 World's Greatest Leaders." In 2016, he was named to Massachusetts General Hospital Cancer Center's "The One Hundred" list. In 2017, he was chosen as one of "The Bloomberg 50." In 2019, he was named one of OncLive's "Giants of Cancer Care." He has received numerous awards from professional societies including the American Society of Clinical Oncology, American Association for Cancer Research, National Coalition for Cancer Survivorship, LUNGevity Foundation, American Society for Clinical Pharmacology and Therapeutics, National Organization

for Rare Disorders, Reagan-Udall Foundation for the FDA, the FDA Alumni Association, University of Chicago Cancer Research Foundation, and the Regulatory Affairs Professionals Society.

Edith A. Perez, MD
Mayo Clinic and Bolt Biotherapeutics

Edith A. Perez, M.D., a translational researcher and cancer treatment specialist, is the Chief Medical Officer of Bolt Biotherapeutics, Inc. and Professor of Medicine at Mayo Clinic. As Chief Medical Officer of Bolt Biotherapeutics, Inc., Dr. Perez is responsible for clinical strategy and development, regulatory affairs, pharmacovigilance, biostatistics, and medical affairs for the company's diverse clinical development and early-stage immuno-oncology pipeline. Previously, Dr. Perez was Vice President and Head of the BioOncology medical unit at Genentech, Inc., overseeing all U.S. hematology and oncology medical affairs, and with her team, was involved in leading numerous trials and launching six drugs, including Gazyva®, Perjeta®, Alecensa® and Tecentriq®.

Dr. Perez spent the first 20 years of her career at the Mayo Clinic where she was active in teaching, research, and patient care, with a research focus in breast cancer and translational biomarkers. She was the principal investigator of the N9831 trial, which was one of the pivotal studies that demonstrated the impact of adding trastuzumab (Herceptin®) to improve disease-free and overall survival for patients with early-stage HER-2 positive breast cancer. Dr. Perez has authored several hundred research articles in journals, books, and abstracts and has lectured at national and international meetings. She serves on the editorial boards of multiple academic journals and has also been involved in diversity leadership initiatives with ASCO and AACR and currently serves as the Chair of the Health Equity Committee for Stand Up to Cancer.

Dr. Perez earned her M.D. from the University of Puerto Rico School of Medicine in San Juan and completed her residency in internal medicine at the Loma Linda University Medical Center in California. She served as a general internist in the Division of National Health Services Corps in Los Angeles and completed her Hematology/Oncology fellowship at the UC Davis School of Medicine. Dr. Perez also has pursued leadership, management, and executive development at The Wharton School of the University of Pennsylvania and Harvard Kennedy School in Boston. Dr. Perez is board certified in internal medicine, medical oncology, and hematology.

Karen Reckamp, MD, MS
Cedars-Sinai Cancer Center

Karen L. Reckamp, MD, MS is Clinical Professor in Medicine, Director of the Division of Medical Oncology at Cedars-Sinai Medical Center. She is also the Associate Director of Clinical Research for the Cedars-Sinai Cancer Center, and Medical Oncology Director of the Women's Guild Lung Institute at Cedars Sinai Medical Center.

She received a master's degree in Clinical Investigation from the department of Biomathematics at UCLA. Dr. Reckamp also serves as the Associate Director of Clinical Research for the Samuel Oschin Comprehensive Cancer Institute (SOCCI). She obtained my medical degree at the University of Chicago, Pritzker School of Medicine in 1998 with AOA distinction, and trained in Internal Medicine at Washington University's Barnes-Jewish Hospital. Dr. Reckamp completed fellowship training in Hematology/Oncology at the David Geffen School of Medicine, UCLA in June 2004, and completed a Master of Science degree in Clinical Research (MSCR).

Dr. Reckamp serves as Chair for the Association of American Cancer Institute's Physician Clinical Leadership Initiative. She leads many phase I, II and III studies funded by the NCI, internal funds and industry. Dr. Reckamp is a member of ASCO, AACR, International Association for the Study of Lung Cancer, and SWOG. She is vice Chair of the SWOG Lung MAP

platform. She participated in the ASCO Leadership Development Program and led the Scientific Committee for metastatic lung cancer for the ASCO annual meeting. Dr. Reckamp has been the past recipient of many honors including American Lung Association, Lung Force Honoree in 2018. She has also authored or co-authored many manuscripts in the field of Thoracic Oncology in high impact journals, including the New England Journal of Medicine and Journal of Clinical Oncology.

Kristen Rosati, JD
Partner, Coppersmith Brockelman PLC

Kristen is considered one of the nation's leading "Big Data" attorneys. She has deep experience in research data sharing, clinical research compliance, biobanking, and healthcare and genomic privacy, and advises clients on compliance with federal, state and international data privacy laws. Kristen is a sought-after national speaker on these issues and is a Past President and Fellow of the American Health Law Association, the nation's largest health care legal organization.

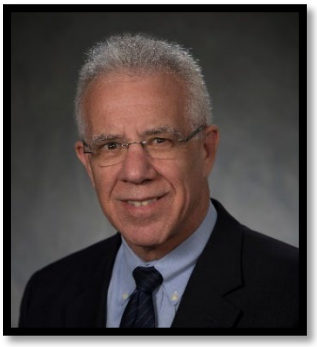
Eric Rubin, MD, PhD
New England Journal of Medicine

Eric Rubin has been Editor-in-Chief at the New England Journal of Medicine since 2019 after serving as an Associate Editor for several years. He is an infectious disease physician at the Brigham and Women's Hospital and a tuberculosis researcher at the Harvard TH Chan School of Public Health.

Eric holds an AB degree from Harvard College and MD and PhD degrees from Tufts University. He was a resident and clinical fellow at the Massachusetts General Hospital and a postdoctoral fellow at Harvard Medical School. Eric was the Irene Heinz Given Professor and Chair of the Department of Immunology and Infectious Disease before joining NEJM full time but continues to do lab work at the Harvard Chan School. He is Professor of Medicine at the Harvard Medical School and Adjunct Professor at the Harvard TH Chan School of Public Health. He is a Fellow of the American Academy of Microbiology and a member of the National Academy of Medicine.

Richard L. Schilsky, MD, FACP, FSCT, FASCO *(Co-Chair)*
University of Chicago

Dr. Schilsky is the former Chief Medical Officer and Executive Vice President of the American Society of Clinical Oncology (ASCO), and served as its President from 2008-2009. He spent the majority of his career at the University of Chicago, joining the faculty in 1984, and serving in many leadership positions including as Associate Dean for Clinical Research in the Biological Sciences Division, Chief of Hematology/Oncology in the Department of Medicine, and Director of the University of Chicago Cancer Research Center. From 1995 to 2010, Dr. Schilsky served as Chair of the Cancer and Leukemia Group B (CALGB), a national cooperative clinical research group funded by the National Cancer Institute (NCI). He has extensive experience working with both the NCI and the Food and Drug Administration (FDA) having served as a member and Chair of the NCI Board of Scientific Advisors, member of the NCI Clinical and Translational Research Committee, and member and Chair of the Oncologic Drugs Advisory Committee (ODAC) of the FDA. Dr. Schilsky has served on the editorial boards of many cancer journals, including *the Journal of Clinical Oncology*, and presently serves on the editorial board of the *New England Journal of Medicine*. Dr. Schilsky received his BA from the University of Pennsylvania and MD from the University of Chicago Pritzker School of Medicine.



Lawrence N. Shulman, MD, MACP, FASCO
University of Pennsylvania Abramson Cancer Center

Lawrence N. Shulman, MD, MACP, FASCO, is Professor of Medicine in the Perelman School of Medicine at the University of Pennsylvania, associate director at the Abramson Cancer Center, and director of the Center for Global Cancer Medicine. He is a member of Penn's Center for Cancer Care Innovation. He is the immediate past chair of the Commission on Cancer and serves on the National Cancer Policy Forum of the National Academy. He is the former chair of the American Society of Clinical Oncology Quality of Care Committee and the Commission on Cancer's Quality Integration Committee. He serves as Senior Oncology Advisor to the non-profit organization Partners In Health (PIH). The PIH mission includes the establishment of national cancer treatment programs with the Ministries of Health in Rwanda and Haiti, programs for which he plays a seminal leadership role. He sits on the Vice Chancellor's Advisory Council for Rwanda's University for Global Health Equity. In addition, he helps to lead the development of the national oncology program in Botswana through the Botswana-UPenn Partnership. He is a former member of ASCO's International Affairs Committee and their Task Force on Global Oncology as an Academic Career. He led the World Health Organization's review and revision of their Essential Medicines for Cancer from 2014-2017. He received his MD from Harvard Medical School and trained in Hematology and Oncology at the Beth Israel Hospital in Boston, MA.

Ellen V. Sigal, PhD
Friends of Cancer Research

Ellen V. Sigal, PhD, is Chairperson and Founder of Friends of Cancer Research (*Friends*), a think tank and advocacy organization based in Washington, DC. *Friends* drives collaboration among partners from every healthcare sector to power advances in science, policy, and regulation that speed life-saving treatments to patients. During the past 25 years, *Friends* has been instrumental in the creation and implementation of policies ensuring patients receive the best treatments in the fastest and safest way possible.

Dr. Sigal holds leadership positions with a broad range of cancer advocacy, public policy organizations and academic health centers including the MD Anderson Cancer Center External Advisory Board and the inaugural board of advisors for the George Washington University's Milken Institute of Public Health. She also currently serves on the Board of the Foundation for the National Institutes of Health, where she chairs its Governance Committee.

Dr. Sigal most recently served for 10 years as Chair of the inaugural board of directors of the Reagan-Udall Foundation, which was authorized by congress and designed to modernize medical product development, accelerate innovation, and facilitate public private partnerships. enhance product safety in collaboration with the U.S. Food and Drug Administration.

Beginning in 2010, Dr. Sigal was appointed for two consecutive six-year terms on the Board of Governors of the Patient Centered Outcomes Research Institute (PCORI) as a representative of patients and health consumers. She also served on the Advisory Board of the COVID-19 Evidence Accelerator – a partnership between the Reagan-Udall Foundation and Friends of Cancer Research with participation from the FDA. Additionally, over the past several years Dr. Sigal was named to then Vice President Biden's Cancer Moonshot Blue Ribbon Panel, to the Parker Institute for Immunotherapy Advisory Group.

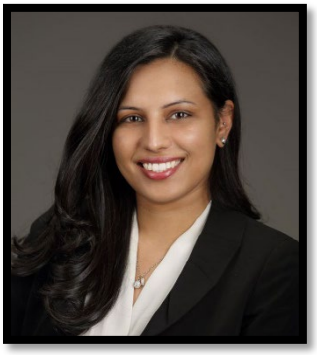
Ellen received her PhD in Russian History from Rutgers University and holds a BA from Brooklyn College.

Dinah S. Singer, PhD
National Cancer Institute

Dr. Dinah Singer is the Deputy Director for Scientific Strategy and Development of the National Cancer Institute (NCI), National Institutes of Health (NIH) and a Senior Investigator and Chief of the Molecular Regulation Section of the Experimental Immunology Branch, NCI. From 1999 until 2019, she served as the Director of the NCI Division of Cancer Biology. Currently, Dr. Singer also serves as the Acting Director of the Center for Strategic Scientific Initiatives and oversees NCI's Center for Research Strategy, the Center for Cancer Training, and the Center to Reduce Cancer Health Disparities. Dr. Singer's research interests are in regulation of gene expression and molecular immunology. She has trained many post-doctoral fellows, post-baccalaureate students and high school students who have gone on to successful scientific careers.

Dr. Singer has provided leadership and support for many NCI programs. She co-chaired the 2016 Blue Ribbon Panel of the Cancer Moonshot and continues to lead and manage implementation of the Cancer Moonshot. Dr. Singer led the formation of NCI's Cancer Grand Challenges partnership with CRUK. She initiated and provides oversight for NCI's Serological Sciences Network, the nation's largest coordinated effort to study the immune response to COVID-19.

Dr. Singer received her B.S. from the Massachusetts Institute of Technology and her Ph.D. from Columbia University. She serves on various scientific and editorial boards and is a member of the American Association of Cancer Research and American Association of Immunologists. Dr. Singer has received numerous awards and serves in leadership positions on a variety of trans-NIH scientific and administrative committees.



Harpreet Singh, MD
United States Food and Drug Administration

Dr. Singh is a medical oncologist and Director of the Division of Oncology 2 in the Office of Oncologic Diseases. As Director of the Division of Oncology 2, Dr. Singh oversees drug development for thoracic and head and neck cancer, neurologic tumors, pediatric solid tumors, and rare oncologic cancers. She is also Associate Director for Cancer in Older Adults and Special Populations in the Oncology Center of Excellence (OCE) at the FDA.

Dr. Singh received her M.D. degree from the University of Southern California. She completed her Internal Medicine residency and Geriatrics fellowship at USC, followed by a Medical Oncology fellowship at the National Cancer Institute. Dr. Singh maintains her clinical credentials at the National Cancer Institute.

Heidi Smith, MSHS
Novartis Pharmaceuticals

Heind "Heidi" Smith is currently the VP, Head of USMA Launch Excellence and Medical Operations at Novartis Pharmaceuticals Corporation. Heidi joined Novartis in 2009 in the Oncology Global Drug Development organization. Heidi then transitioned to the Oncology Global Medical Affairs organization and later to the US Oncology Medical organization as US VP, Head of the Center of Operations Research and Excellence (US CORE). She was most recently VP, Head Clinical Operations & Governance and serving ad-interim for US VP Head, Scientific Knowledge Management. Heidi has over 20 years of industry experience including roles in the hospital and CRO environments, and in pharmaceutical companies across multiple therapeutic areas.

She holds a BA degree in Biology from Drew University in New Jersey and a Masters in Health Sciences from George Washington University.

Craig L. Tendler, MD
Janssen Pharmaceutical Companies of Johnson & Johnson

Craig Tendler, M.D. is Vice President and Global Head of Clinical Development, Diagnostics, and Medical Affairs for the Oncology Therapeutic Area at Janssen Research & Development, one of the Janssen Pharmaceutical Companies of Johnson & Johnson. In this position, he is responsible for creating and overseeing robust development plans, including optimal integration of biomarkers and diagnostics, and comprehensive data generation activities for all products in the oncology portfolio, from proof of concept through registration and lifecycle management. He works closely with teams in early development and the disease areas of focus to implement a seamless end-to-end oncology clinical research strategy that incorporates compelling science, broad clinical trial access to diverse populations, and addresses areas of high unmet medical need.

Prior to this role, Craig served as Vice President of Medical Affairs for Tibotec Therapeutics and then Ortho-Biotech, where he led medical affairs teams in lifecycle management and data generation for the Janssen Virology and Oncology franchises.

Craig has overseen and coordinated more than 30 major drug approvals by national regulatory agencies, including at least ten NDAs by the US Food and Drug Administration (FDA). He and his have team worked in collaboration with the FDA and the European Medicines Agency to secure the worldwide approvals of Janssen's treatments in prostate cancer, hematologic malignancies, as well as for lung and bladder cancer. Further, together with his team, Craig has been instrumental in achieving 11 FDA breakthrough designations for accelerating the early development of promising investigational medicines intended for the treatment of serious oncology conditions.

Prior to joining Janssen, Craig served as the Vice President of Oncology Clinical Research and Chair of the Oncology Licensing Committee at the Schering-Plough Research Institute. In addition to his pharmaceutical industry experience, he has served as Assistant Professor of Pediatrics/Hematology-Oncology at the Mount Sinai School of Medicine in New York City and as a research fellow at the National Cancer Institute in Bethesda, Maryland.

Craig earned his undergraduate degree from Cornell University, and graduated from the Mount Sinai School of Medicine, New York City, with high honors and induction into the Alpha Omega Alpha Medical Society.

Robert A. Winn, MD
Virginia Commonwealth University Massey Cancer Center

Robert A. Winn, MD, is the Director of Virginia Commonwealth University (VCU) Massey Comprehensive Cancer Center. He is also senior associate dean for cancer innovation at the VCU School of Medicine, and professor at the Division of Pulmonary Disease and Critical Care Medicine at VCU. His current basic science research focuses on the translational aspects of the role that proliferation pathways and cellular senescence play in lung cancer. As a pulmonologist, Robert is committed to community-engaged research centered on eliminating health disparities. He is a principal investigator on several community-based projects funded by the NIH and National Cancer Institute. Robert is the president-elect of the Association of American Cancer Institutes (AACI); Chair of the National Cancer Policy Forum of the National Academies of Sciences, Engineering, and Medicine; and a member of the Board of Directors for the American Cancer Society and LUNGevity Foundation. Robert holds a BA from the University of Notre Dame and an MD from the University of Michigan Medical School in Ann Arbor. He completed an internship and residency in internal medicine at Rush-Presbyterian-St. Luke's Medical Center in Chicago and a fellowship in pulmonary and critical care medicine at the University of Colorado Health Sciences Center in Denver.

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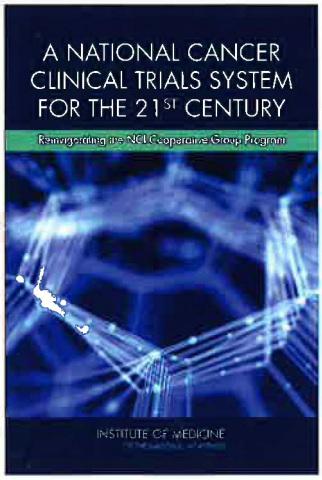
A National Cancer Clinical Trials System for the 21st Century

Reinvigorating the NCI Cooperative Group Program



Advances in biomedical research continue to create significant opportunities for improving the detection, treatment, and prevention of cancer. But generating knowledge is only a start. Clinical trials that test the safety and therapeutic benefit of promising treatments are essential in translating new knowledge into tangible benefits for patients with cancer—the second leading cause of death in the United States, behind heart disease.

For the past 50 years, the National Cancer Institute's (NCI) Clinical Trials Cooperative Group Program has played a key role in developing new and improved cancer therapies. The program's 10 Cooperative Groups conduct clinical trials through networks of cancer centers and community oncology practices across the country. More than 25,000 patients and thousands of clinical investigators participate in the program's clinical trials annually. Its efforts complement the clinical trials that pharmaceutical and biotechnology companies conduct, particularly by addressing questions that are less likely to be among industry's top priorities. In recent years, however, many stakeholders—including clinical investigators, patient advocates, Cooperative Group leadership, industry participants, as well as the NCI—have expressed concerns that the program is falling short of its potential to conduct the timely, large-scale, innovative clinical trials needed to improve patient care. As a result, NCI asked the Institute of Medicine (IOM) to assess the state of cancer clinical trials, review the Cooperative Group Program, and provide advice on improvements.

For the past 50 years, the NCI Clinical Trials Cooperative Group Program has played a key role in developing new and improved cancer therapies. . . . however, many stakeholders have expressed concerns that the program is falling short of its potential to conduct the timely, large-scale, innovative clinical trials needed to improve patient care.

Building on a Strong Foundation

The IOM's report, *A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program*, reviews the roles of the various stakeholders involved in cancer clinical trials and recommends a series of changes across the board. The report's authoring committee envisions a dynamic system that efficiently responds to emerging scientific knowledge; involves broad cooperation of stakeholders; and leverages evolving technologies to provide high-quality, practice-changing research. Clinical trial participation would be desirable for patients and physicians because it would provide access to innovative therapies that reflect patient preferences and are reimbursed. The report emphasizes the need to maintain a robust, standing cancer clinical trials network by preserving the historical strengths of the Cooperative Group Program while improving components that are not working well. The following overarching goals should guide improvement efforts:

- Improving the speed and efficiency of the design, launch, and conduct of clinical trials
- Making optimal use of scientific innovations
- Improving selection, prioritization, support, and completion of clinical trials
- Fostering expanded participation of both patients and physicians

Improving Speed and Efficiency

Clinical trials are complex endeavors that involve hundreds of steps and lengthy, iterative review processes by multiple oversight bodies with varying objectives and responsibilities. Inefficiencies in the processes used to develop, launch, and conduct clinical trials often lead to long delays. The average time required to design, approve, and activate a cancer clinical trial is two years. Given the pace at which new scientific findings are emerging, a trial concept may become outdated in that period. The committee recommends that protocol development be coordinated and streamlined by implementing the processes proposed by the Operational Efficiency Working Group.

The committee stresses the need to move beyond cooperation to integration by reorganizing clinical trial structures and operations into a truly national trials network. Among its recommended actions for improving overall operations, the report calls for consolidating many of the administrative functions and processes within the Cooperative Group Program, streamlining government oversight of trials, and enhancing collaboration among stakeholders. NCI should lead in instituting the necessary changes, but other federal agencies such as the Food and Drug Administration, as well as academic centers, community practices, and the pharmaceutical industry, will need to be involved in improving the system. NCI also should expand drug distribution and implement standardized case report forms and remote data capture systems to aid trial efficiency.

Incorporating Innovative Science

Progress in the treatment of cancer patients depends on the effective incorporation of scientific advances into clinical trials. For example, to achieve the goals of targeted cancer therapy, biomarkers (predictors of a response to a particular therapeutic intervention) increasingly are being used to select which treatment strategy is most likely to benefit individual patients. To advance this field, NCI should, among other actions, mandate that biospecimens collected from patients in the course of Cooperative Group trials be submitted to standardized central biorepositories supported by a national inventory and a defined peer-review process for accessing specimens for study.

The Cooperative Groups should lead in developing and testing innovative designs for clinical trials that evaluate multiple therapies, combinations of therapies, and biomarkers. The National Institutes of Health, including NCI, should take a

The report's authoring committee envisions a dynamic system that efficiently responds to emerging scientific knowledge; involves broad cooperation of stakeholders; and leverages evolving technologies to provide high-quality, practice-changing research.

more systematic, multidisciplinary, and dynamic approach when developing standards for new scientific methods and technologies used in trials, to ensure appropriate and consistent use.

Prioritizing and Supporting Trials

The increasingly complex environment in which cancer clinical trials are conducted has created considerable challenges for the Cooperative Group Program. Inefficient interactions among the various stakeholders are contributing to delays in the system. To increase the speed of advances in oncology care, NCI should shift its primary focus from oversight to the facilitation of Cooperative Group trials. As part of this effort, NCI should streamline processes for prioritizing, selecting, and supporting clinical trials and for enrolling patients quickly after a trial is launched. Participating sites should be credentialed to enroll patients in any high-priority trial, and sites with low patient accrual should be eliminated.

NCI should allocate a larger portion of its research portfolio to the Cooperative Group Program. However, the trial prioritization and selection process should be strengthened so that only well-designed clinical trials that have the greatest possibility of improving survival and quality of life for cancer patients are undertaken. Launching only the highest-ranked trials would improve quality, speed advances, and ensure that patients are enrolling in the most meaningful and potentially beneficial trials.

Patient and Physician Participation

A robust clinical trials infrastructure depends on a critical mass of physicians and patients willing to participate. But participation is not the norm today. Participation in clinical trials requires substantial resources and support staff. Clinical investigators and sites are not adequately reimbursed for the costs of participating in Cooperative Group trials. Moreover, the current system does not adequately reward collaborative work, and at academic medical centers, clinical investigation often is accorded less value than either basic research or patient care. Given the limits in funding and capacity of the system, it is unrealistic to expect all or most clinicians to participate in trials, but those who are motivated to do so should be supported and encouraged. NCI and other stakeholders should explore and expand approaches for reducing career and financial concerns, such as providing salary support for protected research time.

Even if patients are eligible for trials and are informed about the option by their physicians, they may decline participation because of financial concerns, as coverage of patient care costs in clinical trials by health insurers is inconsistent. Among other actions, federal and state health benefits plans, private health insurers, and the Centers for Medicare and Medicaid Services should establish consistent payment policies to cover patient care costs (except for specific study-related costs that should be paid for by the drug or device manufacturer) in clinical trials approved through the NCI prioritization mechanism. As a quid pro quo, pri-

vate insurers should be able to eliminate coverage of experimental therapies delivered outside of the clinical trial setting, but any such limitation in coverage should not affect off-label use that is backed by evidence from clinical trials published in the scientific literature, as evidence-based off-label use constitutes the standard of care for many cancer therapies and is therefore not experimental.

Conclusion

Improved treatments for cancer will be delayed and patient lives will be lost unnecessarily unless the efficiency and effectiveness of the clinical trials system improves. The implementation of the report's collective recommendations will reinvigorate the NCI Clinical Trials Cooperative Group Program and strengthen its position as a critical component of the translational pathway from scientific discovery to improved treatment outcomes for patients with cancer. Modifying any single element of the Program or the clinical trials process will not suffice; changes across the board are urgently needed. All stakeholders, including physicians, patients, and health care insurers, as well as NCI, other federal agencies, academia, foundations, and industry, must reevaluate their roles and responsibilities in cancer clinical trials and work together to develop an improved, efficient multidisciplinary trials system. The health of nearly 1.5 million patients diagnosed with cancer in the U.S. each year depends on these efforts.

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500 Fifth Street, NW
Washington, DC 20001
TEL 202.334.2352
FAX 202.334.1412
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Forum on DRUG DISCOVERY, DEVELOPMENT, and TRANSLATION

NATIONAL CANCER POLICY FORUM

Optimizing Public-Private Partnerships for Clinical Cancer Research
October 17-18, 2023

Additional Resources

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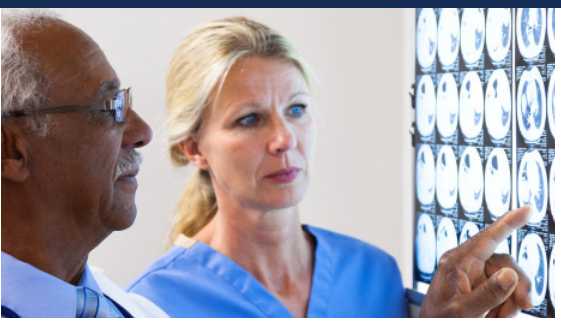
NATIONAL CANCER POLICY FORUM

ABOUT THE FORUM



The National Cancer Policy Forum serves as a trusted venue in which experts can identify emerging high-priority policy issues in cancer research and cancer care and work collaboratively to examine those issues through convening activities focused on opportunities for action. The Forum provides a continual focus within the National Academies on cancer, addressing issues in science, clinical medicine, public health, and public policy that are relevant to the goal of reducing the cancer burden, through prevention and by improving the care and outcomes for those diagnosed with cancer. Forum activities inform the cancer community and the public about critical policy issues through workshops and published reports. The Forum has members with a broad range of expertise in cancer, including patient advocates, clinicians, and basic, translational, and clinical scientists. Members represent patients, federal agencies, academia, professional organizations, nonprofits, and industry.

The Forum has addressed a wide array of topics, including:

- enhancing collaborations to accelerate research and development;
- improving the quality and value of care for patients who have been diagnosed with or are at risk for cancer;
- developing tools and technologies to enhance cancer research and care; and
- examining factors that influence cancer incidence, mortality, and disparities.

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NATIONAL ACADEMIES Sciences Engineering Medicine

Upcoming and Recent Workshops

Biological Effectors of Social Determinants of Health in Cancer: Identification and Mitigation

March 20-21, 2024

Biological effectors of social determinants of health (SDOH) interact and impact cancer risk, treatment outcomes, and health equity. Workshop presentations and discussions will consider opportunities to advance health equity in cancer by identifying promising avenues for future research, as well as policies and interventions aimed at mitigating the negative impacts of the SDOH in cancer.

Workshop website in development

Optimizing Public-Private Partnerships for Clinical Cancer Research

Collaborative workshop convened by:
National Cancer Policy Forum
Forum on Drug Discovery, Development, and Translation

October 17-18, 2023

Public-private partnerships have the potential to more effectively leverage public funding and resources, increase the breadth and depth of research, and effect a more rapid translation from basic discoveries to public health applications. Industry, government, nonprofit, and academic organizations could each make important and unique contributions to this endeavor. This workshop will examine opportunities to enhance and foster public-private partnerships for clinical cancer research and consider lessons learned from examples of public-private collaborations in oncology or other fields that have helped to advance clinical research and improve patient outcomes.

Workshop website

Assessing and Advancing Progress in the Delivery of High-Quality Cancer Care

Collaborative workshop co-hosted by:
National Cancer Policy Forum
American Society of Clinical Oncology

October 5-6, 2023

This year marks the 10-year anniversary of the Institute of Medicine (IOM) report, *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis*, and the ability of the cancer care delivery system to provide high-quality cancer care to all patients remains elusive. This workshop—co-sponsored by the National Cancer Policy Forum and the American Society of Clinical Oncology—was an opportunity for the cancer care community to discuss persistent barriers to achieving excellent and equitable cancer care for all, and additional actions that could be taken to implement the 2013 recommendations. Workshop presentations and discussions also identified aspects of cancer care that have changed over the past decade and where new strategies are needed to improve the quality of care.

Workshop website

Developing a Multidisciplinary and Multispecialty Workforce for Patients with Cancer, from Diagnosis to Survivorship

Collaborative workshop convened by:
National Cancer Policy Forum
Global Forum on Innovation in Health Professional Education

July 17-18, 2023

Patients living with and beyond cancer often require care from a wide range of clinicians as they navigate cancer diagnosis, treatment, and survivorship care. A multispecialty and multidisciplinary workforce is critical to ensuring that all patients with cancer receive high-quality care.

This workshop examined opportunities to improve equitable access to multispecialty, multidisciplinary care for patients living with and beyond cancer. Workshop presentations and discussions focused on strategies to expand and strengthen the multispecialty and multidisciplinary workforce, particularly in underserved areas; approaches for enhancing health professional education across the spectrum of non-oncology clinicians to include best practices for the care of patients with cancer; opportunities for collaboration and information-sharing among members of a patient's health care team across specialties and disciplines; payment and care delivery models to facilitate coordination and collaboration; and opportunities to strengthen the evidence base about the array of adverse effects of cancer and cancer treatment on patient outcomes, as well as interventions aimed at mitigating these effects.

Workshop videos and presentations

The Impact of the Dobbs Decision on Cancer Care Webinar Series

The National Cancer Policy Forum hosted a webinar series to discuss the downstream effects of the U.S. Supreme Court ruling, Dobbs v. Jackson Women's Health Organization, on access to reproductive health care in the context of cancer care.

- **How Abortion Restrictions Affect Patients and Care Delivery | July 11, 2023**
- **Health System and Workforce Effects | July 25, 2023**
- **Ethical, Legal, & Social Implications | August 31, 2023**

Webinar Series Website

Recent Workshops

The Potential Contribution of Cancer Genomics Information to Community Investigations of Unusual Patterns of Cancer

Collaborative workshop convened by:
National Cancer Policy Forum
Roundtable on Genomics and Precision Health

April 13, 2023

This workshop examined the opportunities to apply genomic and epigenomic biomarkers of environmental exposures associated with unusual patterns of cancer, particularly in pediatric populations. The workshop was sponsored by the Division of Environmental Health Science and Practice in the National Center for Environmental Health at the Centers for Disease Control and Prevention and was convened to provide background information to assist the CDC in revising their Guidelines for Examining Unusual Patterns of Cancer and Environmental Concerns.

Workshop videos and presentations
Proceedings

Incorporating Integrated Diagnostics into Precision Oncology Care

Collaborative workshop convened by:
National Cancer Policy Forum
Computer Science and Telecommunications Board
Board on Human-Systems Integration

March 6-7, 2023

Innovations in the diagnostic specialties have the potential to reshape cancer diagnosis and enable precision therapy. Spurred by advances in informatics, there are opportunities to combine information from imaging, pathology, and molecular testing. Multidisciplinary collaboration among pathologists, radiologists, and oncologists supplemented by machine-learning based tools could facilitate a more precise understanding of a patient's diagnosis, and what treatment strategies may be most effective to improve outcomes. Integrated diagnostics may also improve patient access to subspecialty expertise, particularly in community-based settings of cancer care. This workshop convened members of the cancer community better define the purpose, goals, and components of integrated diagnostics.

Workshop videos and presentations

Addressing Resistance in the Development of Cancer Immune Modulator Therapeutics

Collaborative workshop convened by:
National Cancer Policy Forum
Forum on Drug Discovery, Development, and Translation

November 14-15, 2022

Many patients who initially respond to immunotherapy treatment may develop resistance to treatment over time. The reasons for the development of resistance are not fully understood, and resistance continues to pose a major threat to further advances in the field of immunotherapy for cancer treatment. This workshop gave participants in the cancer research and cancer care an opportunity to examine the current challenges related to resistance to immunotherapies and to discuss potential policy options that could help overcome these challenges.

Workshop videos and presentations

Advancing Progress in Cancer Prevention and Risk Reduction

June 27-28, 2022

This workshop considered the current state of knowledge on risk factors for cancer and best practices for cancer prevention and risk reduction. Workshop sessions focused on strategies to implement population-based and clinic-based prevention, with exemplar programs in both settings. Participants also examined opportunities to spur progress in cancer prevention and risk reduction.

Workshop videos and presentations
Proceedings

Family Caregiving for People With Cancer and Other Serious Illnesses

Collaborative workshop convened by:
National Cancer Policy Forum
Roundtable on Quality Care for People with Serious Illness
Forum on Aging, Disability, and Independence

May 16-17, 2022

This workshop used cancer as a lens to examine issues that affect family caregivers for people with serious illnesses. Presentations and discussions included: strategies to better capture, understand, and act on family caregiver input and experience to improve patient care and to support family caregivers; research and policy opportunities to better support family caregiving; and strategies to better embed a health equity focus in family caregiving research, policy and practice.

Workshop videos and presentations
Proceedings

FORUM SPONSORS

- Centers for Disease Control and Prevention
- National Institutes of Health/National Cancer Institute
- American Association for Cancer Research
- American Cancer Society
- American College of Radiology
- American Society of Clinical Oncology
- Association of American Cancer Institutes
- Association of Community Cancer Centers
- Bristol-Myers Squibb
- Cancer Support Community
- Flatiron Health
- Merck
- National Comprehensive Cancer Network
- National Patient Advocate Foundation
- Novartis Oncology
- Oncology Nursing Society
- Partners in Health
- Pfizer Inc
- Sanofi
- Society for Immunotherapy of Cancer

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Baylor College of Medicine

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National Cancer Institute

S. Gail Eckhardt, M.D., FASCO
Baylor College of Medicine

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American Society of Clinical Oncology

Roy S. Herbst, M.D., Ph.D.
Yale University

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Memorial Sloan Kettering Cancer Center

Chanita Hughes-Halbert, Ph.D.
University of Southern California

Roy A. Jensen, M.D.
The University of Kansas; Association of American Cancer Institutes

Randy A. Jones, Ph.D., R.N., FAAN
University of Virginia

Beth Y. Karlan, M.D.
University of California, Los Angeles

Samir N. Khleif, M.D.
Georgetown University; Society for Immunotherapy of Cancer

Scott M. Lippman, M.D.
University of California, San Diego

Elena Martinez, Ph.D.
University of California, San Diego

Larissa Nekhlyudov, M.D., M.P.H.
Brigham & Women's Hospital; Dana-Farber Cancer Institute; Harvard Medical School

Randall Oyer, M.D.
University of Pennsylvania; Penn Medicine Lancaster General Health; Association of Community Cancer Centers

Cleo A. Ryals, Ph.D.
Flatiron Health

Richard L. Schilsky, M.D., FASCO
ASCO TAPUR Study; University of Chicago

Julie Schneider, Ph.D.
Oncology Center of Excellence, Food and Drug Administration

Susan M. Schneider, Ph.D., R.N., AOCN®
Duke University

Lawrence N. Shulman, M.D., MACP, FASCO
University of Pennsylvania

Heidi Smith, M.H.S., B.A.
Novartis Pharmaceuticals

Katrina Trivers, Ph.D., M.S.P.H.
Centers for Disease Control and Prevention

Robin Yabroff, Ph.D.
American Cancer Society

FORUM STAFF

Sharyl Nass, Ph.D.
Forum Co-Director
Senior Director, Board on Health Care Services

Erin Balogh, M.P.H.
Forum Co-Director

Jennifer Zhu, M.S.
Associate Program Officer

Emma Wickland, M.P.H.
Research Associate

Anna Adler, B.S.
Senior Program Assistant

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Senior Program Assistant

Torrie Brown, B.A.
Program Coordinator

Julie Wiltshire, B.S.
Senior Finance Business Partner

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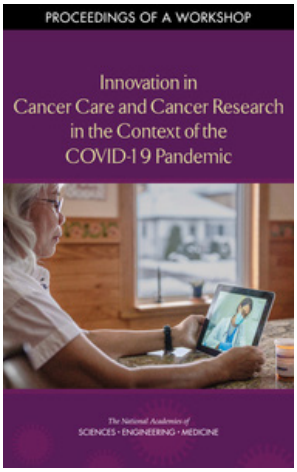
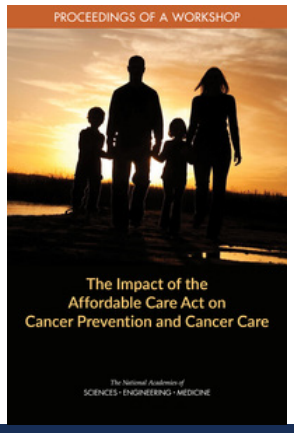
NATIONAL CANCER POLICY FORUM

WORKSHOP PROCEEDINGS AND RELATED PUBLICATIONS





WORKSHOP PROCEEDINGS

2023

Incorporating Integrated Diagnostics into Precision Oncology Care (In Process)

Addressing Resistance in the Development of Cancer Immune Modulator Therapeutics (In Process)

The Potential Contribution of Cancer Genomics Information to Community Investigations of Unusual Patterns of Cancer: Proceedings of a Workshop

Advancing Progress in Cancer Prevention and Risk Reduction: Proceedings of a Workshop

Realizing the Potential of Genomics across the Continuum of Precision Health Care: Proceedings of a Workshop

2022

Family Caregiving for People with Cancer and Other Serious Illnesses: A Workshop

Innovation in Electronic Health Records for Cancer Care, Research, and Surveillance: A Workshop

Promoting Health Equity in Cancer Care: Proceedings of a Workshop

The Role of Companion Animals as Sentinels for Predicting Environmental Exposure Effects on Aging and Cancer Susceptibility in Humans: Proceedings of a Workshop

Innovation in Cancer Care and Cancer Research in the Context of the COVID-19 Pandemic: Proceedings of a Workshop

Impact of the Affordable Care Act on Cancer Prevention and Cancer Care: Proceedings of a Workshop

2021

Addressing the Adverse Consequences of Cancer Treatment: Proceedings of a Workshop

Opportunities and Challenges for Using Digital Health Applications in Oncology: Proceedings of a Workshop

Improving the Evidence Base for Treatment Decision Making for Older Adults with Cancer: Proceedings of a Workshop— in Brief

Advancing Progress in the Development and Implementation of Effective, High-Quality Cancer Screening: Proceedings of a Workshop

Drug Research and Development for Adults Across the Older Age Span: Proceedings of a Workshop

2020

Reflections on Sharing Clinical Trial Data: Challenges and a Way Forward: Proceedings of a Workshop

Applying Big Data to Address the Social Determinants of Health in Oncology: Proceedings of a Workshop

Health Literacy and Communication Strategies in Oncology: Proceedings of a Workshop

Enhancing Scientific Reproducibility in Biomedical Research Through Transparent Reporting: Proceedings of a Workshop

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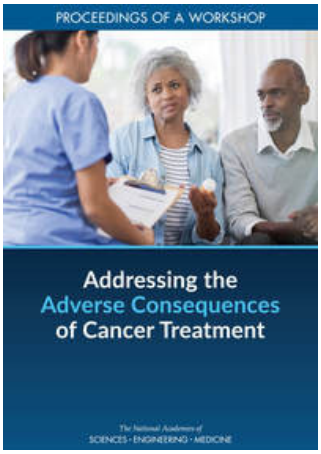
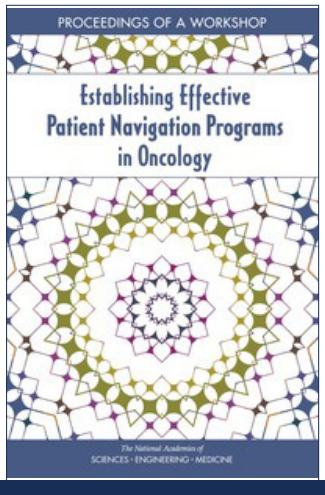




WORKSHOP PROCEEDINGS

2019

Developing and Sustaining an Effective and Resilient Oncology Careforce: Proceedings of a Workshop

Advancing Progress in the Development of Combination Cancer Therapies with Immune Checkpoint Inhibitors: Proceedings of a Workshop

Improving Cancer Diagnosis and Care: Clinical Application of Computational Methods in Precision Oncology: Proceedings of a Workshop

2018

Improving Cancer Diagnosis and Care: Patient Access to Oncologic Imaging and Pathology Expertise and Technologies: Proceedings of a Workshop

Establishing Effective Patient Navigation Programs in Oncology: Proceedings of a Workshop

Long-Term Survivorship Care After Cancer Treatment: Proceedings of a Workshop

2017

The Drug Development Paradigm in Oncology: Proceedings of a Workshop

Cancer Care in Low-Resource Areas: Cancer Treatment, Palliative Care, and Survivorship Care: Proceedings of a Workshop

Implementation of Lung Cancer Screening: Proceedings of a Workshop

Incorporating Weight Management and Physical Activity Throughout the Cancer Care Continuum: Proceedings of a Workshop

2016

Policy Issues in the Clinical Development and Use of Immunotherapy for Cancer Treatment: Proceedings of a Workshop

Cancer Care in Low-Resource Areas: Cancer Prevention and Early Detection: Workshop Summary

Appropriate Use of Advanced Technologies for Radiation Therapy and Surgery in Oncology: Workshop Summary

2015

Comprehensive Cancer Care for Children and Their Families: Summary of a Joint Workshop by the Institute of Medicine and the American Cancer Society

Policy Issues in the Development and Adoption of Biomarkers for Molecularly Targeted Cancer Therapies: Workshop Summary

Assessing and Improving the Interpretation of Breast Images: Workshop Summary

Role of Clinical Studies for Pets with Naturally Occurring Tumors in Translational Cancer Research: Workshop Summary

2014

Ensuring Patient Access to Affordable Cancer Drugs: Workshop Summary

Contemporary Issues for Protecting Patients in Cancer Research: Workshop Summary

2013

Identifying and Addressing the Needs of Adolescents and Young Adults with Cancer: Workshop Summary

Implementing a National Cancer Clinical Trials System for the 21st Century: Second Workshop Summary

Sharing Clinical Research Data: Workshop Summary

Delivering Affordable Cancer Care in the 21st Century: Workshop Summary

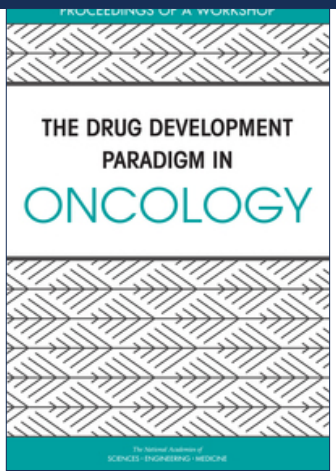
Reducing Tobacco-Related Cancer Incidence and Mortality: Workshop Summary

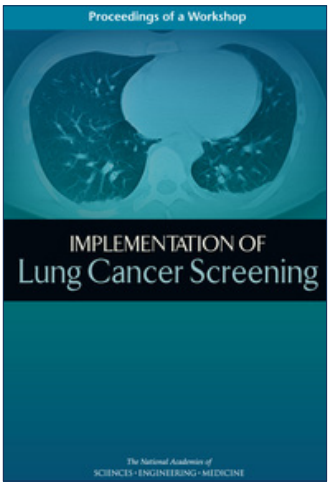
2012

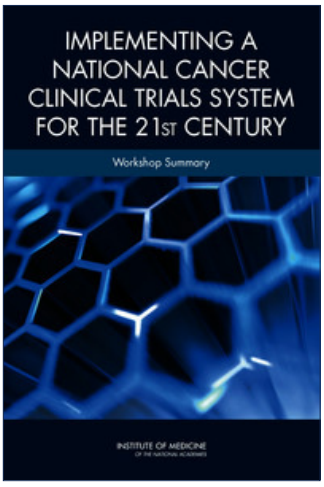
The Role of Obesity in Cancer Survival and Recurrence: Workshop Summary

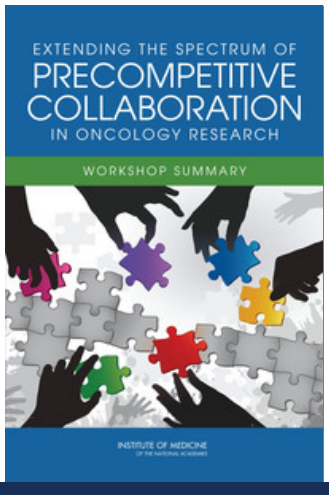
Informatics Needs and Challenges in Cancer Research: Workshop Summary

Facilitating Collaborations to Develop Combination Investigational Cancer Therapies: Workshop Summary









WORKSHOP PROCEEDINGS

2011

Implementing a National Cancer Clinical Trials System for the 21st Century: Workshop Summary
Patient-Centered Cancer Treatment Planning: Improving the Quality of Oncology Care: Workshop Summary
The National Cancer Policy Summit: Opportunities and Challenges in Cancer Research and Care
Nanotechnology and Oncology: Workshop Summary

2010

Direct-to-Consumer Genetic Testing (with the National Research Council): Summary of a Workshop
Extending the Spectrum of Precompetitive Collaboration in Oncology Research: Workshop Summary
A Foundation for Evidence-Driven Practice: A Rapid Learning System for Cancer Care: Workshop Summary
Policy Issues in the Development of Personalized Medicine in Oncology: Workshop Summary

2009

Assessing and Improving Value in Cancer Care: Workshop Summary
Ensuring Quality Cancer Care Through the Oncology Workforce: Sustaining Care in the 21st Century: Workshop Summary
Multi-Center Phase III Clinical Trials and the NCI Cooperative Group Program: Workshop Summary

2008

Implementing Colorectal Cancer Screening: Workshop Summary
Improving the Quality of Cancer Clinical Trials: Workshop Summary

2007

Cancer-Related Genetic Testing and Counseling: Workshop Proceedings
Cancer in Elderly People: Workshop Proceedings
Implementing Cancer Survivorship Care Planning: Workshop Summary

2006

Effect of the HIPAA Privacy Rule on Health Research: Proceedings of a Workshop
Developing Biomarker-Based Tools for Cancer Screening, Diagnosis, and Treatment: Workshop Summary

RELATED WORK

CONSENSUS STUDY REPORTS BUILDING ON NCPF WORK

Childhood Cancer and Functional Impacts Across the Care Continuum (2021)
Report: nap.edu/catalog/25944

Diagnosing and Treating Adult Cancers and Associated Impairments (2021)
Report: nap.edu/catalog/25956

Guiding Cancer Control: A Path to Transformation (2019)
Report: nap.edu/catalog/25438

Making Medicines Affordable: A National Imperative (2017)
Report: nap.edu/catalog/24946

Biomarker Tests for Molecularly Targeted Therapies: Key to Unlocking Precision Medicine (2016)
Report: nap.edu/catalog/21860

Ovarian Cancers: Evolving Paradigms in Research and Care (2016)
Report: nap.edu/catalog/21841

Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis (2013)
Report: nap.edu/catalog/18359

Evolution of Translational Omics: Lessons Learned and the Path Forward (2012)
Report: nap.edu/catalog/13297

A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program (2010)
Report: nap.edu/catalog/12879

Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease (2010)
Report: nap.edu/catalog/12869

Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research (2009)
Report: nap.edu/catalog/12458

Cancer Biomarkers: The Promises and Challenges of Improving Detection and Treatment (2007)
Report: nap.edu/read/11892

INDIVIDUALLY AUTHORED PUBLICATIONS BUILDING ON NCPF WORK

Independent, individually authored articles arising from NCPF workshops—and consensus studies building on NCPF work—include:

2022

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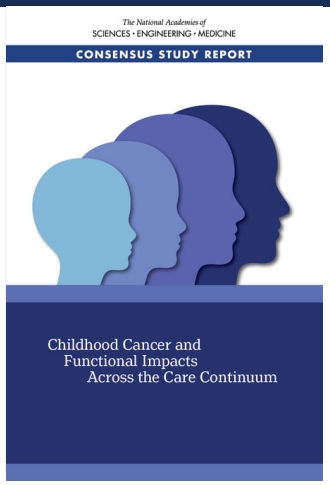

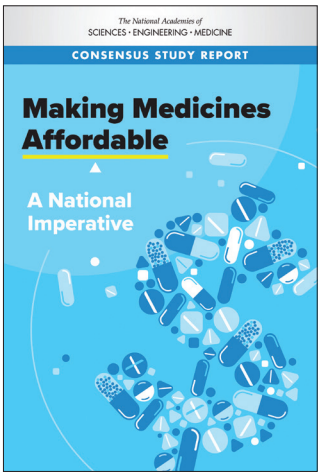

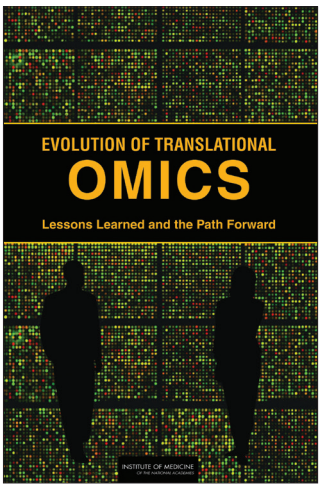

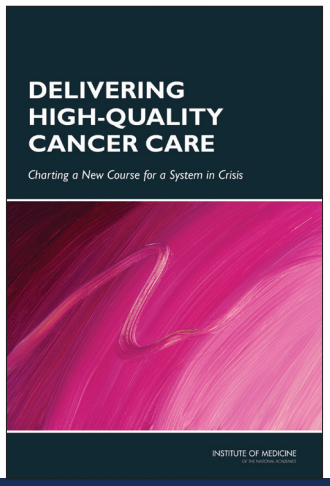

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Forum on
DRUG DISCOVERY, DEVELOPMENT, and TRANSLATION

ABOUT THE FORUM

The Forum on Drug Discovery, Development, and Translation (the forum) of the National Academies of Sciences, Engineering, and Medicine (the National Academies) was created in 2005 by the National Academies Board on Health Sciences Policy to foster communication, collaboration, and action in a neutral setting on issues of mutual interest across the drug research and development lifecycle. The forum membership includes leadership from the National Institutes of Health, the U.S. Food and Drug Administration, industry, academia, consortia, foundations, journals, and patient-focused and disease advocacy organizations.

Through the forum's activities, participants have been better able to bring attention and visibility to important issues, explore new approaches for resolving problem areas, share information and find common ground, and work together to develop ideas into concrete actions and new collaborations.

Forum work is based on four thematic priorities:

Spurring INNOVATION and IMPLEMENTATION

Revolutionary advances in biomedical research and technology present new and exciting opportunities for the discovery and development (R&D) of new therapies for patients. The evolution of health care is expanding possibilities for integration of clinical research into the continuum of clinical care and new approaches are enabling the collection of data in real-world settings. Innovative modalities, such as digital health technologies and artificial intelligence applications, can now be leveraged to overcome challenges and advance clinical research. The forum unites key stakeholders to identify opportunities, address bottlenecks, and spur innovation in drug discovery, development, and translation.

Increasing PERSON-CENTEREDNESS and EQUITY

There is much greater awareness around the need for more person-centered and inclusive approaches that prioritize lived experience, equity, and justice in the discovery, development, and translation of new treatments. The forum seeks to center priorities of people living with disease and those who have been traditionally under-represented or excluded from the clinical trials enterprise, advance the science of patient input, and help bring to fruition innovations that better address the needs of patients.

Promoting COLLABORATION and HARMONIZATION

The forum provides a neutral platform for communication and collaboration across sectors and disciplines to better harmonize efforts throughout the drug R&D life cycle. It does this by convening a broad and evolving set of stakeholders to help integrate patients, caregivers, researchers, trialists, community practitioners, sponsors, regulators, payers, patient and disease advocacy groups, and others into the continuum of research and clinical care. The forum also strives to enable shared decision-making and ensure that patients have input into research questions, researchers have insight into clinical practice, and practitioners are engaged in the clinical trials enterprise.

Enhancing the WORKFORCE and INFRASTRUCTURE

The forum has fostered the development of strategies to improve the discipline of innovative regulatory science and continues to focus on building a workforce that is diverse, adaptable, and resilient. Considerable opportunities remain to improve and expand the evolving clinical trials workforce and infrastructure, integrate community-based practices, and engage early-career scientists and clinicians in drug discovery, development, and translation. The forum will continue to anticipate and promote adaptation to changes in the infrastructure of health care delivery.

For more information about the Forum on Drug Discovery, Development, and Translation, please visit at:

NATIONALACADEMIES.ORG/DRUGFORUM

Health and Medicine Division
Board on Health Sciences Policy

NATIONAL ACADEMIES Sciences Engineering Medicine

Forum Membership

Gregory Simon (Co-Chair)
Kaiser Permanente Washington Health Research Institute

Ann Taylor (Co-Chair)
Retired

Barbara E. Bierer
Harvard Medical School

Linda S. Brady
National Institute of Mental Health, NIH

John Buse
University of North Carolina Chapel Hill School of Medicine

Luther T. Clark
Merck & Co., Inc.

Barry S. Coller
The Rockefeller University

Tammy R.L. Collins
Burroughs Wellcome Fund

Thomas Curran
Children's Mercy, Kansas City

Richard T. Davey
National Institute of Allergy and Infectious Diseases, NIH

Katherine Dawson
Biogen

James H. Doroshow
National Cancer Institute, NIH

Jeffrey M. Drazen
New England Journal of Medicine

Steven Galson
Retired

Carlos Garner
Eli Lilly and Company

Sally L. Hodder
West Virginia University

Tesheia Johnson
Yale School of Medicine

Lyric A. Jorgenson
Office of the Director, NIH

Esther Krofah
FasterCures, Milken Institute

Lisa M. LaVange
University of North Carolina Gillings School of Global Public Health

Aran Maree
Johnson & Johnson

Cristian Massacesi
AstraZeneca

Ross McKinney, Jr.
Association of American Medical Colleges

Joseph P. Menetski
Foundation for the NIH

Anaeze C. Offodile II
Memorial Sloan Kettering Cancer Center

Sally Okun
Clinical Trials Transformation Initiative

Arti K. Rai
Duke University School of Law

Klaus Romero
Critical Path Institute

Joni Rutter
National Center for Advancing Translational Sciences, NIH

Susan Schaeffer
The Patients' Academy for Research Advocacy

Anantha Shekhar
University of Pittsburgh School of Medicine

Ellen V. Sigal
Friends of Cancer Research

Mark Taisey
Amgen Inc.

Amir Tamiz
National Institute of Neurological Disorders and Stroke, NIH

Pamela Tenaerts
Medable

Majid Vakilynejad
Takeda

Jonathan Watanabe
University of California Irvine School of Pharmacy and Pharmaceutical Sciences

Alastair J. Wood
Vanderbilt University

Cris Woolston
Sanofi

Joseph C. Wu
Stanford University School of Medicine

Forum Staff

Carolyn Shore, Ph.D.
Forum Director

Kyle Cavagnini, Ph.D.
Associate Program Officer

Noah Ontjes, M.A.
Research Associate

Melvin Joppy
Senior Program Assistant

NATIONAL ACADEMIES Sciences Engineering Medicine

NATIONAL CANCER POLICY FORUM

Biological Effectors of Social Determinants of Health in Cancer: Identification and Mitigation: A Workshop

March 20-21, 2024

Keck Center Room 100
500 Fifth Street, NW
Washington, DC 20001

Workshop Statement of Task

A National Academies of Sciences, Engineering, and Medicine planning committee will plan and host a 1.5-day public workshop that will examine the biological effectors of social determinants of health (SDOH) in cancer and consider how the interaction of these two factors influences cancer risk, treatment outcomes, and health equity. The workshop will feature invited presentations and panel discussions on topics that may include:

- Examples of biological factors that could mediate the effects of SDOH, such as responses to chronic stress that affect immune function and inflammation, and their impact on cancer risk and outcomes.
- Emerging data on epigenetic changes stemming from social disadvantages and environmental stressors across the life course that may increase risk of cancer and poor outcomes.
- Opportunities to effectively measure and validate biomarkers for the impact of biological effectors of SDOH on cancer risk and outcomes.
- Linkages between biological impacts of SDOH and policy factors that influence health outcomes, such as access to health insurance coverage.
- Existing and emerging interventions to mitigate the biological effects of SDOH and the policy implications of these approaches.
- Research gaps and opportunities for interdisciplinary approaches to identify and mitigate biological effectors of SDOH in cancer.

The planning committee will develop the agenda for the workshop sessions, select and invite speakers and discussants, and moderate the discussions. A proceedings of the presentations and discussions at the workshop will be prepared by a designated rapporteur in accordance with institutional guidelines.

Provisional Planning Committee:

Chanita Hughes-Halbert, University of Southern California (Co-Chair)
Stanton Gerson, Case Western Reserve University (Co-Chair)
Karen Basen-Enquist, University of Texas MD Anderson Cancer Center
Smita Bhatia, University of Alabama at Birmingham
Cathy Bradley, Colorado School of Public Health
Otis Brawley, Johns Hopkins University
Gwen Darien, National Patient Advocate Foundation
Scarlett Lin-Gomez, University of California, San Francisco
Larissa Nekhlyudov, Brigham and Women's Hospital/Dana-Farber Cancer Institute, Harvard Medical School
Lisa Richardson, Centers for Disease Control and Prevention
Cleo Ryals, Flatiron Health
Rob Winn, Virginia Commonwealth University Massey Cancer Center
Robin Yabroff, American Cancer Society
Clayton Yates, Johns Hopkins University

Project Webpage Pending