

Addressing Resistance in the Development of Cancer Immune Modulator Therapeutics

A Collaborative Workshop Convened by the National Cancer Policy Forum
and the Forum on Drug Discovery, Development, and Translation



A WORKSHOP

NATIONAL ACADEMIES Sciences
Engineering
Medicine

Addressing Resistance in the Development of Cancer Immune Modulator Therapeutics

November 14 | 8:30am – 4:30pm ET
November 15 | 8:30am – 12pm ET

Link to view webcast:

<https://www.nationalacademies.org/event/11-14-2022/addressing-resistance-in-the-development-of-cancer-immune-modulator-therapeutics-a-workshop>

November 14, 2022

Dear Colleagues,

Welcome to the National Academies of Sciences, Engineering, and Medicine workshop on *Addressing Resistance in the Development of Cancer Immune Modulator Therapeutics*. This workshop is being convened by the National Cancer Policy Forum in collaboration with the Forum on Drug Discovery, Development, and Translation. Presentations and discussions will examine the current challenges of resistance to immune modulator therapies for cancer and discuss potential policy opportunities to improve immunotherapy development.

We welcome your involvement in the workshop. Please use the microphones in the room or the chat box on our website (<https://www.nationalacademies.org/event/11-14-2022/addressing-resistance-in-the-development-of-cancer-immune-modulator-therapeutics-a-workshop>) 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 a lively discussion about countering resistance and advancing progress in cancer treatment using immune modulator therapeutics.

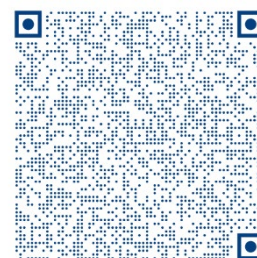
Sincerely,

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

George J. Weiner, MD
C.E. Block Chair of Cancer Research
Professor of Internal Medicine
Professor of Pharmaceutical Science
Experimental Therapeutics
Director, Holden Comprehensive Cancer Center
University of Iowa

Addressing Resistance in the Development of Cancer Immune Modulator Therapeutics

A Collaborative Workshop Convened by the
National Cancer Policy Forum
Forum on Drug Discovery, Development, and Translation



2101 Constitution Ave., NW
Lecture Room
Washington, DC 20418

AGENDA

November 14, 2022 - Eastern Time Zone	
8:00 am	BREAKFAST AND REGISTRATION
8:30 am	WELCOME FROM THE NATIONAL CANCER POLICY FORUM <i>Planning Committee Co-Chairs:</i> Samir N. Khleif, Georgetown University Medical Center George J. Weiner, Holden Comprehensive Cancer Center
8:40 am	KEYNOTE: IMPLICATIONS OF SCIENTIFIC INNOVATIONS ON HIGH-QUALITY CANCER CARE AND PATIENT OUTCOMES Elizabeth M. Jaffee, President's Cancer Panel; Johns Hopkins University (Virtual)
9:00 am	SESSION 1: CRITERIA TO MOVE SINGLE AGENTS INTO CLINICAL TRIALS <i>Co-Moderators:</i> Samir N. Khleif, Georgetown University Medical Center Tom Curran, Children's Mercy Research Institute; Kansas City University Talk 1: Single Agent Activity Anti-PD1 - Suzanne L. Topalian, Johns Hopkins University Talk 2: Single Agent Activity Anti-Lymphocyte Activation Gene-3 - Hussein Tawbi, MD Anderson Cancer Center Talk 3: Single Agent Activity #2 (TNFR agonists-OX40) - John Janik, Cullinan Oncology Talk 4: Perspective on Resistance to CAR-T - Stephan A. Grupp, Children's Hospital of Philadelphia (Virtual) Talk 5: Regulatory Perspective: What has Changed and What is Missing? - Peter F. Bross, Center for Biological Evaluation and Research, Food and Drug Administration Panel Discussion
10:30 am	BREAK

WORKSHOP WEBSITE AND BRIEFING MATERIALS

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10:40 am	SESSION 2: CURRENT CHALLENGES AND OPPORTUNITIES: SELECTION OF EXPERIMENTAL AGENTS IN COMBINATIONS <i>Co-Moderators:</i> Gideon Blumenthal, Merck Marc Theoret, Oncology Center of Excellence, Food and Drug Administration Talk 1: Preclinical Models and Understanding Immunotherapy Efficacy - Samir N. Khleif, Georgetown University Medical Center Talk 2: IO/IO Combinations Versus Other Modalities to Overcome Anti-PD1 Resistance - Jane A. Healy, Merck Research Labs Talk 3: Anti-PD1 and IDO1 Inhibition: Lessons Learned - Jason J. Luke, University of Pittsburgh Medical Center Talk 4: Intra-Lesional Approaches: Regulatory Issues - George J. Weiner, Holden Comprehensive Cancer Center Panel Discussion
12:00 pm	LUNCH BREAK
1:00 pm	SESSION 3: CURRENT CHALLENGES AND OPPORTUNITIES: BIOMARKERS AND SURROGATE ENDPOINTS <i>Co-Moderators:</i> Kimryn Rathmell, Vanderbilt University Medical Center Chris Boshoff, Pfizer Inc (Virtual) Talk 1: Genetic Biomarkers - Teresa Davoli, NYU Langone Health (Virtual) Talk 2: Diagnostic Imaging - Marius Mayerhoefer, Memorial Sloan Kettering Cancer Center Talk 3: Immune Metabolism - Hildegund C.J. Ertl, The Wistar Institute Talk 4: Novel Surrogate Biomarkers for Immune Therapy Response and Resistance - Kimryn Rathmell, Vanderbilt University Medical Center Talk 5: Current Regulatory Landscape in Biomarkers and Imaging - Reena Philip, Oncology Center of Excellence, Food and Drug Administration Talk 6: Surrogate Endpoint Development Perspective - Nicole Gormley, Center for Drug Evaluation and Research, Food and Drug Administration Panel Discussion
2:40 pm	BREAK

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2:50 pm	SESSION 4: CURRENT CHALLENGES AND OPPORTUNITIES: THE ROLE OF DATA AND COMPUTATIONAL TOOLS <i>Co-Moderators:</i> Nancy E. Davidson, Fred Hutchinson Cancer Center Julie R. Gralow, American Society of Clinical Oncology Talk 1: Regulatory and Access Considerations in Mining Big Data - Ahmad A. Tarhini, H. Lee Moffitt Cancer Center and Research Institute Talk 2: Advanced Computing Tools - Jack D. Hidary, SandboxAQ (Virtual) Talk 3: Data Driven Approaches for Modeling Response and Resistance - Dana Pe'er, Memorial Sloan Kettering Cancer Center Talk 4: Leveraging Real World Data to Characterize Immune-Related Adverse Events - Prakirthi Yerram, Flatiron Health Talk 5: Leveraging Artificial Intelligence - Usama Fayyad, Institute for Experiential Artificial Intelligence. Northeastern University Panel Discussion
4:20 pm	Closing Remarks <i>Planning Committee Co-Chairs:</i> Samir N. Khleif, Georgetown University Medical Center George J. Weiner, Holden Comprehensive Cancer Center
4:30 pm	ADJOURN TO RECEPTION – NAS GREAT HALL
November 15, 2022 - Eastern Time Zone	
8:00 am	BREAKFAST AND REGISTRATION
8:30 am	WELCOME AND OVERVIEW OF DAY 2 <i>Planning Committee Co-Chairs:</i> Samir N. Khleif, Georgetown University Medical Center George J. Weiner, Holden Comprehensive Cancer Center
8:40 am	SESSION 5: CRITERIA TO ASSESS CANCER IMMUNOTHERAPY COMBINATIONS IN EARLY-PHASE CLINICAL TRIALS: TYPES OF CLINICAL TRIAL DESIGNS NEEDED FOR REGULATORY APPROVAL <i>Co-Moderators:</i> Roy S. Herbst, Yale Comprehensive Cancer Center (Virtual) Hedvig Hricak, Memorial Sloan Kettering Cancer Center Talk 1: Novel Immunotherapy Clinical Trial Design Keith T. Flaherty, Massachusetts General Hospital; Harvard Medical School

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	Talk 2: Public Private Partnership Perspective - Roy Herbst, Yale Comprehensive Cancer Center (Virtual) Talk 3: Regulatory Considerations for Cancer Immunotherapeutic Development - Marc Theoret, Oncology Center of Excellence, Food and Drug Administration Talk 4: National Cancer Institute Perspective - Elad Sharon, NCI Cancer Therapy Evaluation Program Talk 5: Industry Perspective - Alexandra Snyder, Genentech Biomedicines Talk 6: Challenges of Trial Design: Incorporating Pharmacodynamics - Jedd Wolchok, Weill Cornell Medicine (Virtual) Panel Discussion
10:10 am	BREAK
10:20 am	SESSION 6: PANEL DISCUSSION REFLECTIONS ON THE WORKSHOP AND NEXT STEPS TO OVERCOME RESISTANCE TO IMMUNE MODULATOR THERAPIES FOR CANCER TREATMENT <i>Co-Moderators:</i> George J. Weiner, Holden Comprehensive Cancer Center Scott M. Lippman, University of California, San Diego Panelists: Session 1: Samir N. Khleif and Tom Curran Session 2: Gideon Blumenthal and Marc Theoret Session 3: Kimryn Rathmell and Chris Boshoff (Virtual) Session 4: Nancy E. Davidson and Julie R. Gralow Session 5: Roy S. Herbst (Virtual) and Hedvig Hricak Open Discussion
11:50 am	CLOSING REMARKS <i>Planning Committee Co-chairs:</i> Samir N. Khleif, Georgetown University Medical Center George J. Weiner, Holden Comprehensive Cancer Center
12:00 pm	ADJOURN

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PLANNING COMMITTEE ROSTER

Addressing Resistance in Immune Modulator Therapies for Cancer Treatment: A Workshop

Samir N. Khleif, MD (Co-Chair)

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

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Director
Holden Comprehensive Cancer Center
C.E. Block Chair of Cancer Research
Professor, Departments of Internal Medicine and Pharmaceutical Science Experimental Therapeutics
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Global Regulatory Affairs for Oncology
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Chris Boshoff, MD, PhD, FMedSci

Chief Development Officer, Oncology & Rare Disease
Global Product Development
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Senior Vice President
Executive Director and Chief Scientific Officer
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Donald J. Hall Eminent Scholar in Pediatric Research
Children's Mercy Kansas City
Professor, Department of Pediatrics, UMKC School of Medicine
Professor, Department of Cancer Biology, University of Kansas School of Medicine
Adjunct Professor of Biomedical Sciences
Kansas City University

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Senior Vice President and Professor
Clinical Research Division
Fred Hutchinson Cancer Center
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Professor and Head
Division of Medical Oncology
University of Washington

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Executive Vice President
Chief Medical Officer
American Society of Clinical Oncology

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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

Hedvig Hricak, MD, PhD

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Hugh Jackson Morgan Professor of Medicine and Biochemistry
Chair, Department of Medicine
Physician-in-Chief
Vanderbilt University Medical Center

Marc Theoret, MD

Deputy Director
Oncology Center of Excellence
Food and Drug Administration

SPEAKER AND MODERATOR ROSTER

Addressing Resistance in Immune Modulator Therapies for Cancer Treatment: A Workshop

Gideon Blumenthal, MD

Vice President
Oncology Global Regulatory Affairs and Clinical Safety
Merck

Chris Boshoff, MD, PhD

Chief Development Officer, Oncology & Rare Disease
Global Product Development
Pfizer Inc

Peter F. Bross, MD

Chief, Oncology Branch
Office of Tissues and Advanced Therapeutics,
Center for Biologics Evaluation and Research
Food and Drug Administration

Tom Curran, PhD, FRS

Senior Vice President
Executive Director and Chief Scientific Officer
Children's Research Institute
Donald J. Hall Eminent Scholar in Pediatric Research
Children's Mercy, Kansas City
Professor, Department of Pediatrics
University of Missouri-Kansas City School of Medicine
Professor, Department of Cancer Biology
University of Kansas School of Medicine
Adjunct Professor of Biomedical Sciences
Kansas City University

Nancy E. Davidson, MD

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Clinical Research Division
Fred Hutchinson Cancer Center
Raisbeck Endowed Chair for Collaborative Cancer
Research
Professor and Head, Division of Medical Oncology
Department of Medicine
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Teresa Davoli, PhD

Assistant Professor
Institute for Systems Genetics
New York University Langone Health

Hildegund C.J. Ertl, MD

Professor
The Wistar Institute

Usama Fayyad, PhD

Executive Director
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Director of Clinical Research
Massachusetts General Hospital Cancer Center
Professor of Medicine
Harvard Medical School

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Division of Hematologic Malignancies II
Acting Associate Director of Oncology Endpoint
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Director, Susan S. and Stephen P. Kelly Center for
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Medical Director, Cell and Gene Therapy Lab
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Professor of Pharmacology
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Technology Researcher and Entrepreneur
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Chair
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John Janik

Cullinan Oncology

Elizabeth M. Jaffee, MD, FAACR, FACP, FAAAS

Chair
President's Cancer Panel
Deputy Director
Johns Hopkins Sidney Kimmel Comprehensive
Cancer Center
Co-Director
Gastrointestinal Cancers Program
Professor of Oncology
Johns Hopkins University

Samir N. Khleif, MD (Co-Chair)

Biomedical Scholar
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Georgetown University Medical Center
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Moores Cancer Center
Distinguished Professor of Medicine
Senior Associate Dean and Associate Vice
Chancellor for Cancer Research and Care
Chugai Pharmaceutical Chair in Cancer
University of California, San Diego

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Immunotherapy and Drug Development Center
UPMC Hillman Cancer Center
Associate Professor of Medicine
University of Pittsburgh Medical Center
University of Pittsburgh

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Alan and Sandra Gerry Endowed Chair
Scientific Director of the Gerry Metastasis and Tumor
Ecosystems Center
Sloan Kettering Institute
Memorial Sloan Kettering Cancer Center
Investigator
Howard Hughes Medical Institute

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Associate Director
Biomarkers & Precision Oncology
Oncology Center of Excellence
Food and Drug Administration

Kimryn Rathmell, MD, PhD

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Biochemistry
Chair, Department of Medicine
Vanderbilt University Medical Center
Physician-in-Chief
Vanderbilt University Adult Hospital and Clinics

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Cancer Therapy Evaluation Program
Co-Chair
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Implementation Team
Division of Cancer Treatment & Diagnosis
National Cancer Institute

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Generate Biomedicines

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Professor, Oncologic Sciences
University of South Florida Morsani College of Medicine
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Bloomberg-Kimmel Professor of Cancer Immunotherapy
Professor, Surgery and Oncology
Johns Hopkins University School of Medicine
Director
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Associate Director
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George J. Weiner, MD (Co-Chair)

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Professor
Departments of Internal Medicine and Pharmaceutical
Science Experimental Therapeutics
The University of Iowa

Jedd Wolchok, MD, PhD, FASCO

Meyer Director
Sandra and Edward Meyer Cancer Center
Professor of Medicine
Weill Cornell Medicine

Prakirthi Yerram, PharmD, BCOP

Clinical Director
Research Oncology, Real World Evidence
Flatiron Health

SPEAKERS AND PLANNING COMMITTEE BIOSKETCHES



Gideon Blumenthal, MD

Merck

Gideon Blumenthal, MD, is a hematologist oncologist who is currently Vice President, Oncology Global Regulatory Affairs and Clinical Safety, Merck. He has overseen regulatory strategy for pembrolizumab across Genitourinary, Gastrointestinal, Head and Neck Cancer, and Hematologic Malignancies. In addition, he has overseen strategy for belzutifan in VHL and Renal Cell Carcinoma, and investigational agents including vibostolimab, favezelimab and nemtabrutinib. 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.



Chris Boshoff, MD, PhD, FMedSci

Pfizer Inc

Chris Boshoff, MD, PhD, FMedSci, is Chief Development Officer for Pfizer Oncology and Rare Disease. In this capacity, he is responsible for clinical research and development for Pfizer's portfolio of cancer medicines across more than 30 indications. He also leads clinical development across all therapeutic areas in Japan (Development Japan). Dr. Boshoff was formerly Senior Vice President for Immuno-Oncology, Early Development and Translational Oncology at Pfizer where he directed the strategies for early cancer drug

development, precision medicine and immuno-oncology. He has published over 150 original articles covering cancer biology, tumor virology and experimental cancer medicine. He contributed to the early foundational discoveries related to Kaposi's sarcoma-associated herpesvirus (KSHV). Boshoff earned his PhD from the Institute of Cancer Research in London, trained as a medical oncologist at the Royal Marsden and Royal Free Hospitals in London, and served for several years as founding Director of the University College London (UCL) Cancer Institute.



Peter F. Bross, MD

Center for Biologics Evaluation and Research
 Food and Drug Administration

Peter Bross, MD, is Chief of the Oncology Branch in the FDA's Center for Biologics Evaluation and Research (CBER), Office of Tissue and Advanced Therapies (OTAT) and previously worked as a clinical reviewer in the Division of Oncology Drug Products in the Center for Drug Evaluation and Research (CDER). Dr. Bross has expertise in the design and analysis of clinical oncology trials of cellular, tissue and gene therapies, especially cancer vaccines, combination therapies, and companion diagnostics.



Tom Curran, Ph.D

Children's Mercy Research Institute and
 Kansas City University

Tom Curran, Ph.D., holds the Donald J. Hall Eminent Scholar in Pediatric Research and he serves as the Executive Director and Chief Scientific Officer of the Children's Research Institute, Children's Mercy, Kansas City. He is also a Professor of Pediatrics at the University of Missouri-Kansas City School of Medicine. From 1984-1995, Dr. Curran worked at the Roche Institute of Molecular Biology ultimately rising to the position of Associate Director. He then founded the

Department of Developmental Neurobiology at St. Jude Children's Research Hospital where he grew the Translational Brain Tumor Program over the period 1995-2006. He served as Deputy Scientific Director of the Children's Hospital of Philadelphia Research Institute from 2006-2015 and he established the multi-institution Children's Brain Tumor Tissue Consortium. Dr. Curran's research spans the fields of cancer, signal transduction and neurobiology. He discovered and characterized the inducible Fos-Jun oncogenic transcription factor complex and demonstrated its function in diverse signal transduction processes. He also identified reelin, the gene responsible for the classic ataxic mouse mutation, *reeler*, and determined its role in the control of neuronal migration in the developing brain. Over the course of the last two decades, he pioneered the preclinical analysis of Hedgehog Pathway inhibitors for the treatment of pediatric medulloblastoma and transitioned this work into successful Phase I/II human clinical trials. His work is published in 298 papers that have been cited more than 50,000 times. Dr. Curran was President of the American Association for Cancer Research (AACR) in 2000-2001 and he served on the National Cancer Institute Board of Scientific Advisors from 2000-2005. He was elected as a fellow of the American Association for the Advancement of Science (1994), the American Society of Microbiology (1994), the Royal Society, London (2005), the National Academy of Medicine (2009), the American Academy of Arts and Sciences (2012), the Academy

of the American Association for Cancer Research (2013) and as a Corresponding Fellow of the Royal Society of Edinburgh (2021). Dr. Curran has received several awards and honors including, the Passano Foundation Young Scientist Award in 1992, the Outstanding Achievement in Cancer Research award from the AACR in 1993, the Golgi Award from the Camillo Golgi Foundation and the Italian Academy of Neurosciences in 1994 and the Fred Epstein Lifetime Achievement Award from the Children's Brain Tumor Foundation in 2015. Many of his more than 50 trainees now hold senior positions in Academia and Industry.



Nancy E. Davidson, MD
Fred Hutchison Cancer Center

Nancy E. Davidson, MD, is a world-renowned breast cancer researcher who serves as the executive vice president and executive director for clinical affairs and director of the Clinical Research Division at Fred Hutch. She holds the Raisbeck Endowed Chair for Collaborative Research. She also heads the Division of Medical Oncology at the University of Washington School of Medicine and served as president and executive director of Seattle Cancer Care Alliance. She was president of American Society of Clinical Oncology (ASCO) from 2007-2008 and of American Association of Cancer Research (AACR) from 2016-2017. Dr. Davidson completed her MD from Harvard Medical

School, internship at the University of Pennsylvania, residency at Johns Hopkins, and medical oncology fellowship at NIH's National Cancer Institute. She served as a faculty member in the Department of Oncology at Johns Hopkins University School of Medicine from 1986-2009 and held the Breast Cancer Research Chair of Oncology from 1995-2009. From 2009-2016 she served as Hillman Professor of Oncology, Associate Vice Chancellor for Cancer Research and Director of the Cancer Institute at the University of Pittsburgh. She is a member of the National Academy of Medicine and the American Academy of Arts and Sciences.



Teresa Davoli, PhD
NYU Langone Health

Teresa Davoli, PhD, obtained her doctorate in 2013 from The Rockefeller University working with Dr. Titia de Lange on studying how telomere dysfunction promotes aneuploidy during tumorigenesis. During her postdoctoral training, she worked with Dr. Stephen Elledge using genomics approaches to understand the consequences of cancer aneuploidy for tumor formation and for therapy response in cancer patients. In May 2018, Dr. Davoli started her lab

at the Institute for Systems Genetics at NYU School of Medicine in New York. Her lab

uses functional genetics and computational approaches to study the causes and consequences of genomic instability in cancer. Dr. Davoli has received the Weintraub Graduate Student award in 2013 and she was a Helen Hay Whitney Postdoctoral Scholar. Dr. Davoli was a V Foundation Scholar and was also awarded the Melanoma Research Alliance Young Investigator Award, the Breast Cancer Alliance Young Investigator Award.

Her lab focuses on dissecting the causes and consequences of chromosome gains and losses in solid tumors, including oral, colorectal, breast cancer and melanoma. Dr. Davoli proposed for the first time that recurrent chromosome gains and losses in cancer act as driver events (Davoli et al., Cell 2013; Sack, Davoli et al. Cell, 2018). Dr. Davoli recently found that tumors with a high level of aneuploidy tend to be immune cold and to be refractory to immunotherapy (Davoli et al., Science 2017). More recently, through a collaborative effort, her lab found that tumors bearing 9p loss tend to be immune cold and to be refractory to immunotherapy (William et al., PNAS 2021 and Zhao et al., submitted). Her long-term goals are to decipher how aneuploidy can be utilized as a biomarker for therapy response and as a potential target for novel cancer treatments that take advantage of synthetic lethalties associated with the aneuploid state.



Hildegund C.J. Ertl, MD
The Wistar Institute

Dr. Ertl's research centers on developing vaccines for an array of diseases and conditions—including HIV, chronic viral infections, COVID-19 and some forms of cancer—not typically considered to be treated using this approach. These vaccines aim to protect against future infections and look to create new therapies for diseases already affecting people.

Hildegund Ertl came to The Wistar Institute as an associate professor in 1987. A native of Germany, she received her medical degree from University of Göttingen. While in medical school, she began her scientific training as a student in the Max Planck Institute of Experimental Medicine. After research fellowships at the Australian National University and the University of Minnesota, Ertl joined the faculty of Harvard University before transitioning to Wistar. She became a full professor at Wistar in 1996 and holds professorships at the University of Pennsylvania School of Medicine and The Children's Hospital of Philadelphia.



Usama Fayyad, PhD
Northeastern University

Dr. Fayyad joined Northeastern University Khoury College of Computer Science as Professor of the Practice, and the Office of the Provost as the Inaugural Executive Director of the Institute for Experiential AI. He continues as Chairman of Open Insights, a company he founded as a technology and consulting firm in 2008 after leaving Yahoo! to enable enterprises to get value out of their data assets and optimize or create new business models based on the new evolving economy of interactions. Leveraging open source, bigData technology, and strategic consulting, Open Insights deploys data-driven solutions

to grow revenue from Data assets through BigData strategy, new business models on data assets, and deploying data science, AI/ML solutions. Usama served (2017-2019) as Co-Founder & CTO at OODA Health, Inc a VC-funded company aiming to liberate the healthcare system from administrative waste by leveraging AI/automation to create real-time/retail-like experience in payments in healthcare.

From 2013-2016 Usama served as Global Chief Data Officer & Group Managing Director at Barclays Bank in London, after launching the largest tech startup accelerator in MENA following his appointment as Executive Chairman of Oasis500 in Jordan by King Abdullah II in 2010. His background includes Chairman & CEO roles at several startups, including Blue Kangaroo Corp, DMX Group and digiMine Inc.

He was the first person to hold the Chief Data Officer title when Yahoo! acquired his second startup in 2004. At Yahoo! he built the Strategic Data Solutions group and founded Yahoo! Research Labs where much of the early work on BigData made it to open source and led to Hadoop and other open source contributions. He has held leadership roles at Microsoft (1996-2000) and founded the Machine Learning Systems group at NASA's Jet Propulsion Laboratory (1989-2005), where his work on machine learning resulted in the top Excellence in Research award from Caltech, and a U.S. Government medal from NASA.

Usama has published over 100 technical articles on data mining, data science, AI/ML, and databases. He holds over 20 patents and is a Fellow of both the AAAI and the ACM. Usama earned his Ph.D. in Engineering in AI/Machine Learning from the University of Michigan, Ann Arbor. He has edited two influential books on data mining/data science and served as Founding Editor-in-Chief on two key journals. He also served on the boards/advisory boards of private and public companies including: Criteo, Invensense, Exelate, RapidMiner, Stella.AI, Virsec, Silniva, Abe.AI, NetSeer, Choicestream, Medio, Leapyear Technology, Drover, and others. He served on the advisory boards of the Data Science Institute at Imperial College, AAI at UTS, and The University of Michigan College of Engineering National Advisory Board. He serves on the Board Advisory Committee to Nationwide Building Society in the UK and on the Advisory board of the WEF Global Center for Cybersecurity. He is an active angel investor/advisor in many early-stage tech startups across the U.S., Europe and the Middle East.



Keith T. Flaherty, MD

Massachusetts General Hospital Cancer Center
Harvard Medical School

Keith T. Flaherty, MD, is Director of Clinical Research at the Massachusetts General Hospital Cancer Center, and Professor of Medicine at Harvard Medical School. As described in the more than 300 peer reviewed primary research reports he has authored or co-authored, Dr. Flaherty and colleagues made several seminal observations that have defined the treatment of melanoma when they established the efficacy of

BRAF, MEK and combined BRAF/MEK inhibition in patients with metastatic melanoma in a series of New England Journal of Medicine articles for which Dr. Flaherty was the first or senior author. He is the principal investigator of the NCI MATCH trial, the first NCI-sponsored trial assigning patients to targeted therapy independent of tumor type on the basis of DNA sequencing detection of oncogenes. Dr. Flaherty joined the NCI Board of Scientific Advisors in 2018 and AACR Board of Directors in 2019. He serves as editor-in-chief of *Clinical Cancer Research*.



Nicole J. Gormley, MD

Center for Drug Evaluation and Research
Food and Drug Administration

Nicole Gormley, MD, is the Division Director for the Division of Hematologic Malignancies II at the U.S. Food and Drug Administration and serves as the Acting Associate Director of Oncology Endpoint Development in the Oncology Center of Excellence. The Division of Hematologic Malignancies II oversees the drug development of products for the treatment of multiple myeloma, lymphomas, and chronic lymphocytic leukemia. In her role as the Acting Associate Director of Oncology Endpoint Development, Dr. Gormley provides direction, coordination and oversight for scientific and policy efforts related to early endpoint development in oncology.

Dr. Gormley joined the FDA in 2011 and previously served as a clinical reviewer and the Multiple Myeloma Clinical Team Lead. While in these roles, Dr. Gormley actively engaged with the multiple myeloma community on the development of novel endpoints, including minimal residual disease, and methods to address racial disparities. Dr. Gormley completed fellowship training in hematology and critical care at the National Institutes of Health and served as the Deputy Clinical Director at the National Heart, Lung and Blood Institute prior to joining the Food and Drug Administration.



Julie R. Gralow, MD, FACP, FASCO
American Society of Clinical Oncology

Julie Gralow, MD, FACP, FASCO, is the Chief Medical Officer and Executive Vice President of ASCO and brings to her role deep expertise in patient care, research, education, and global health. Previously, she was the Jill Bennett Endowed Professor of Breast Cancer at the University of Washington School of Medicine, Professor in the Clinical Research division of the Fred Hutchinson Cancer Research Center, as well as Director of Breast Medical Oncology at the Seattle Cancer Care Alliance.

Dr. Gralow is strongly committed to advancing equity in cancer care. As founder of the Women's Empowerment Cancer Advocacy Network (WE CAN), she supports patient advocates in low- and middle-resource countries. In addition, she served as an adjunct professor in the University of Washington's Department of Global Health, as a member of the University of Washington's Breast Cancer Equity Initiative, as Medical Director for Women's Cancer-related Population Health at the University of Washington, and as an advisory council member for the Uganda Cancer Institute's adult Hematology/Oncology Fellowship Training Program. Dr. Gralow received the ASCO Humanitarian Award in 2018 for her work in empowering women cancer patients and survivors globally.

She is a recognized leader in breast cancer clinical research, and has conducted clinical trials in breast cancer prevention, treatment, and survivorship. Dr. Gralow served in leadership roles for the SWOG Cancer Research Network funded by the National Cancer Institute (NCI), including as Vice Chair of the Breast Cancer Committee and Executive Officer of Breast and Lung Cancer.

Before joining ASCO full-time, Dr. Gralow served the Society in a variety of volunteer and leadership roles, including chairing the ASCO Academic Global Oncology Task Force, co-chairing the ASCO Resource Stratified Guideline Advisory Group, and serving on the editorial board of the European Society of Medical Oncology (ESMO)/ASCO Global Curriculum in Medical Oncology.

She also has been involved with numerous other nonprofit organizations, including Team Survivor Northwest, an exercise and fitness program for woman cancer survivors which she co-founded in 1995 and serves as Team Physician; a medical advisory committee member for Cierra Sisters African American Support Group; an advisory board member of Global Focus on Cancer; and a Board member of Peace Island Medical Center, a rural access hospital in Washington State.

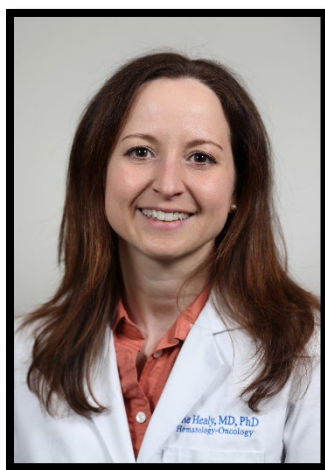
Dr. Gralow received her bachelor's degree from Stanford University and her medical degree from the University of Southern California School of Medicine. She trained in internal medicine at Brigham and Women's Hospital at Harvard Medical School and completed a medical oncology fellowship at University of Washington/Fred Hutchinson Cancer Research Center in Seattle.



Stephan A. Grupp, MD, PhD
Children's Hospital of Philadelphia (CHOP)

Stephan Grupp, MD, PhD, is the Chief of the Cellular Therapy and Transplant Section, Director of the Cancer Immunotherapy Program, and Medical Director of the Cell and Gene Therapy Lab at the Children's Hospital of Philadelphia (CHOP), as well as the Yetta Dietch Novotny Professor of Pediatrics at the University of Pennsylvania Perelman School of Medicine. Dr. Grupp graduated from the University of Cincinnati after completing the MD/PhD program with a PhD in Immunology. He completed pediatric residency at the Boston Children's Hospital, followed by a fellowship in

Pediatric Hematology/Oncology at the Dana Farber Cancer Institute and postdoctoral work in Immunology at Harvard University. He then joined the faculty at Harvard University until 1996, when he came to CHOP. His primary area of clinical research is the use of CAR T and other engineered cell therapies in pediatric cancers and other life-threatening disorders such as sickle cell disease. The work in sickle cell disease includes running the study steering committee for the Vertex trial of whether CRISPR gene-edited stem cells could cure this disease(1). He led all of the pediatric ALL trials of CTL019 (now approved as Kymriah), including the largest and most successful engineered T cell therapy clinical trial conducted to date (2, 3), as well as the global registration trial for CTL019 (4). As a result of this work, he presented the Clinical Perspective at the July 2017 FDA ODAC meeting, at which reviewers voted 10-0 for recommendation of approval for Kymriah in pediatric ALL. His primary laboratory interest is the development of new cell therapy treatments for pediatric cancers. Dr. Grupp was elected to the National Academy of Medicine in 2019.



Jane A. Healy, MD, PhD
Merck Research Labs

Jane A. Healy, MD, PhD, is a physician scientist with a focus in clinical development of small molecule and biologic therapies for cancer. She is a board certified oncologist with >5 years of experience at Merck Oncology early clinical development. She has led numerous clinical programs involving small molecules, vaccines and antibody therapeutics, and has significant experience with First in Human studies, platform trials, and BLA filings. She has transitioned multiple pipeline compounds from early to late clinical development. She is a section lead in early clinical development and leads Merck's anti-TIGIT (vibostolimab) clinical development program.



Roy S. Herbst, MD, PhD
Yale Comprehensive Cancer Center

Roy S. Herbst, MD, PhD, is Ensign Professor of Medicine, Professor of Pharmacology, Chief of Medical Oncology, and Associate Director for Translational Research at Yale Cancer Center (YCC) and Yale School of Medicine, New Haven, CT.

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*. 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. 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 350 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 serves as an elected member of its board of directors and chairs the Tobacco Task Force. 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.



Jack D. Hidary
SandboxAQ

Jack Hidary leads Sandbox AQ, an enterprise SaaS company delivering solutions that leverage quantum tech and AI and run on today's classical computing platforms.

Mr. Hidary is the author of Quantum Computing: An Applied Approach, one of the leading textbooks in the field and is used both in PhD programs and corporate training sessions.

Mr. Hidary is a serial entrepreneur and founder of several tech companies, including EarthWeb/Dice (NYSE: DHX), which he led through a record-breaking IPO. He also co-founded Vista Research which he then sold to Standard and Poors/McGraw-Hill. Mr. Hidary is a trustee of the X Prize Foundation and has been a board member of Trickle Up, which helps thousands of entrepreneurs start small businesses each year. His foundation, The Hidary Foundation, is dedicated to medical oncology research and has supported work at Sloan Kettering and the University of California, San Francisco.

Mr. Hidary has been recognized for his leadership by organizations such as the World Economic Forum, HealthCorps, and Young Presidents' Organization. Jack studied neuroscience at Columbia and subsequently received the Stanley Fellowship in Clinical Neuroscience at NIH where he worked on functional brain imaging and neural networks.



Hedvig Hricak, MD, PhD, Drhc
Memorial Sloan Kettering Cancer Center

Hedvig Hricak, MD, PhD, Drhc (Chair), is Chair, Department of Radiology, Carrol and Carroll and Milton Petrie Chair, Memorial Sloan Kettering Cancer Center, a member of the Molecular Pharmacology and Chemistry Program, Sloan Kettering Institute, and Professor, Gerstner Sloan Kettering Graduate School of Biomedical Sciences, New York, NY. The hallmark of her research career has been the development, validation, and dissemination of new diagnostic imaging techniques, particularly for oncology; she is actively engaged in developing evidence-based imaging guidelines and introducing applications of machine learning and AI for oncology. For her research accomplishments and her efforts to promote national and international education and collaboration in oncologic imaging, she has won numerous awards, including the David Rall Medal, for Distinguished Leadership, from the National Academy of Medicine; five gold medals; and honorary fellowships or memberships in twenty-two international radiological societies. She holds honorary doctorates from the Ludwig Maximilian University, Munich and the University of Toulouse III, Paul Sabatier, Toulouse, France. Hricak is a member of the National Academy of Medicine (formerly the Institute of Medicine) and a “foreign” member of both the Russian Academy of Sciences and the Croatian Academy of Sciences and Arts. She has served on several national advisory boards and councils, including the National Institutes of Health Board of Scientific Counselors, the Scientific Advisory Board of the National Cancer Institute, the Advisory Council of the National Institute of Biomedical Imaging and Bioengineering, and the Nuclear and Radiation Studies Board, National Academy of Sciences. She has also served as chair, co-chair, or member of several Institute of Medicine/National Academy of Medicine and National Academy of Sciences studies.



Elizabeth M. Jaffee, MD, FAACR, FACP, FAAAS
Johns Hopkins University and President’s Cancer Panel

Elizabeth M. Jaffee, MD, FAACR, FACP, FAAAS is an internationally recognized expert in cancer immunology and pancreatic cancer. She is Deputy Director of the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Co-Director of the Skip Viragh Pancreatic Cancer Center and Associate Director of the Bloomberg Kimmel Institute for Cancer Immunotherapy. Her research focus is on developing novel immunotherapies for the treatment and prevention of pancreatic cancer. Dr. Jaffee is a Past President of AACR. She has served on a number of committees at the National Cancer Institute, including the co-chair of the Biden Moonshot Blue Ribbon Panel which identified high impact research priorities for the NCI. She currently serves as Chief

Medical Advisor to the Lustgarten Foundation for Pancreatic Cancer Research. She is the inaugural director of the Convergence Institute for Integrating Technologies and Computational Sciences at Johns Hopkins. Dr. Jaffee is a member of the National Academy of Medicine, a Fellow of the American College of Physicians, a Fellow of American Association for the Advancement of Science, a Fellow of the SITC Academy of Immuno-Oncology and a Fellow of the AACR Academy. Most recently, she was appointed as chair of President Biden's Cancer Panel.



Samir N. Khleif, MD

Georgetown University Medical Center

Samir N. Khleif, MD, 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.



Scott M. Lippman, MD

Moore's Cancer Center, University of California, San Diego

Scott M. Lippman, MD, is Distinguished Professor of Medicine; Director, Moore's Cancer Center (MCC); Senior Associate Dean and Associate Vice Chancellor (AVC) for Cancer Research and Care; and holds the Chugai Pharmaceutical Chair at UC San Diego. He currently serves as adjunct professor at the Salk Institute for Biological Studies, Sanford Burnham Prebys Medical Discovery Institute, and MD Anderson Cancer Center (MDACC). Prior to his recruitment to MCC in 2012, he was on faculty at MDACC for 24 years, including holding the Ellen F. Knisely and the Charles A. LeMaistre Distinguished endowed chairs; and serving as Chair of the Departments of Clinical Cancer Prevention and Thoracic/Head and

Neck Medical Oncology, respectively, for the 16 years preceding his move to MCC. He has led translational, transdisciplinary programs, notably as PI of an NCI Head and Neck (HN) Cancer SPORE, 2 PO1s; and currently leads a Stand Up to Cancer (SU2C) Interception Dream Team award. His research interests include precancer biology, invasive-disease transition and cancer interception, with continuous NCI funding as a PI since 1990.

Dr. Lippman served on the board of directors for the American Association for Cancer Research (AACR), Association of American Cancer Institutes (AACI; and program committee chair), and the Worldwide Innovative Networking (WIN) consortium; and was founding Editor-in-Chief of the AACR journal Cancer Prevention Research, and appointed chair of the AACR cancer prevention committee by then-president Liz Blackburn. Dr. Lippman was a member of the NCI Board of Scientific Advisors Cancer Center Directors Working Group and the NIH Scientific Review Group: NCI Subcommittee A – Cancer Centers, 2016-2019. He held prior positions as: member of the FDA Oncologic Drugs Advisory Committee (ODAC), chair of the NCI CDP Prevention Study Section, member of the NCI Clinical Trials and Translational Research Advisory Committee (CTAC), chair of the SWOG cancer control research committee (and member of Scientific Advisory Board, SAB), and chair of the American Society of Clinical Oncology (ASCO) cancer prevention committee.

Dr. Lippman has published over 450 peer-reviewed primary research articles, received numerous ASCO, AACR, ACS, and other awards and is an elected member of the Association of American Physicians (AAP) and the National Academies of Sciences, Engineering, and Medicine National Cancer Policy Forum. He was chair of the 2017 NCI Pre-Cancer Genome Atlas (PCGA) think tank; and member of the 2021 Pre-Cancer Atlas (PCA) Human Tumor Atlas Network (HTAN) and 2021 AIM-HI Women's Venture Competition (WVC) review panels (the AIM-HI Accelerator Fund's WVC is a first-of-its-kind program that provides funding, coaching and

networking opportunities to women-led oncology start-ups). He has a strong track record, commitment, and passion to train the next generation of scientists and doctors (including serving as member of several PhD thesis committees), and to promote equity, diversity and inclusion in his current/ongoing roles as NCI Comprehensive MCC Director, AVC at UCSD Health System, and nationally in AIM-HI WVC.



Jason J. Luke, MD, FACP

University of Pittsburgh and UPMC Hillman Cancer Center

Jason J. Luke, MD, FACP is an Associate Professor of Medicine at the University of Pittsburgh and UPMC Hillman Cancer Center where he is the Director of the Immunotherapy and Drug Development Center. Dr. Luke specializes in early phase drug development for solid tumors (particularly novel immunotherapeutics and biomarkers of immunotherapy activity) as well as the management of melanoma. Dr. Luke is one of the foremost international investigators in the realm of immuno-oncology, having led clinical trials of immunotherapies including but not limited to anti-PD1/L1, CTLA4, many secondary checkpoints, bispecific approaches

(checkpoint, CD3 and cytokine), metabolism modifiers (IDO, A2Ar/CD73/CD39 and arginase), innate agonists of STING, TLRs and oncolytic virus as well as solid tumor cellular therapies (TCRs and CART). In melanoma, Dr. Luke has designed and led two practice changing trials determining the role of anti-PD1 + CTLA4 after initial anti-PD1 failure (compendium listed in the NCCN) and altering the landscape of melanoma oncology practice across dermatology, surgery and medical oncology via establishment of modern adjuvant therapy with anti-PD1 for node negative stage IIB/C disease (leading to FDA approval). Dr. Luke has been a major contributor toward the investigation of radiation and the microbiome in relation to cancer immunotherapy. Dr. Luke's major translational research focus leverages large scale informatics to advance cancer immunotherapy. Dr. Luke received his M.D. from Rosalind Franklin University of Medicine and Science in Chicago. He then pursued internship and residency at the Boston University Medical Center followed by medicine and medical oncology fellowships at Weill Cornell Medical College and Memorial Sloan-Kettering Cancer Center in New York City. Following fellowship, Dr. Luke was a tenure-track, Type 1 Instructor in Medicine at Harvard Medical School as well as Staff Physician at the Dana-Farber Cancer Institute and Brigham and Women's Hospital in Boston. Thereafter Dr. Luke was an Assistant Professor at the University of Chicago. Dr. Luke is currently Senior Editor at *Clinical Cancer Research*, Associate Editor at the *Journal for Immunotherapy of Cancer* and Skin Cancer Section Editor for the American Cancer Society journal *Cancer*. Dr. Luke is actively involved in several professional societies including SITC (where he sits on the Board of Directors), AACR, ASCO, and the Society for Melanoma Research, having served on the scientific program committees for each. Dr. Luke has RO1 research funding for his laboratory, he is co-PI for the Pittsburgh UM1 LAO and is project 3 clinical co-leader of the Pittsburgh Skin Cancer P50 SPORE, in addition to multiple private and state awards. Dr. Luke has received several awards for research and clinical care including the Melanoma Research Foundation Humanitarian Award, Crain's 40 under 40, DOD Career Development Award, Paul Calabresi Career Development in Clinical Oncology Award (K12),

ASCO Merit Award as well as Young Investigator Awards from the Melanoma Research Alliance, the Cancer Research Foundation and the Conquer Cancer Foundation of ASCO.



Marius Mayerhoefer, MD, PhD
Memorial Sloan Kettering Cancer Center

Marius E. Mayerhoefer, MD, PhD was born in Guessing, Austria. He attended medical school at the Medical University of Vienna, where he graduated in 2004. From 2006 to 2010 he did graduate research, also at the Medical University of Vienna, and attained his PhD in Medical Physics for his research investigating the influence of sequence protocol variations on texture features (radiomics). Dr. Mayerhoefer did his residency training in Radiology in the Department of Radiology of the Medical University of Vienna at the Vienna General Hospital. Dr.

Mayerhoefer has authored and co-authored over 100 peer-reviewed research articles. His main area of expertise is oncologic imaging with PET/MRI, PET/CT, and whole-body MRI, with a focus on blood cancers and neuroendocrine tumors, as well as radiomics and AI. He has presented his work at major scientific meetings across North America, Europe, and Asia. Dr. Mayerhoefer serves on multiple editorial boards of academic journals, including *Investigative Radiology*, *European Radiology*, and *Cancer Imaging*. He is executive board member and treasurer of the European Society of Oncologic Imaging (ESOI), fellow of the International Cancer Imaging Society (ICIS), and member of the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the European Society of Radiology (ESR) and the Radiological Society of North America (RSNA). He served as Associate Professor of Radiology at the Medical University of Vienna until October 2019, when he joined the Department of Radiology of Memorial Sloan Kettering Cancer Center, and is currently the Director of PET/MRI, and Medical Director of the Center for Integrated Metabolic Imaging (CIMI). In August 2022, he was appointed Professor of Radiology at Weill Medical College of Cornell University.



Dana Pe'er, PhD
Memorial Sloan Kettering Cancer Institute

Dana Pe'er, PhD, is Chair of the Computational and Systems Biology Program and Scientific Director of the Gerry Metastasis and Tumor Ecosystems Center at the Sloan Kettering Institute, where she established the Single-cell Analytics Innovation Lab. The Pe'er lab combines single-cell technologies, genomic and imaging data, and machine learning techniques to address fundamental questions in biomedicine. Dr. Pe'er pioneered foundational

approaches to derive cell states, trajectories and future cell fates from biological samples. Her

group has applied these methods to learn how cells reach healthy and aberrant states in development, immunity and cancer, with a focus on tumor heterogeneity, plasticity and tumor-immune interactions. Dr. Pe'er earned her PhD at the Hebrew University and postdoctoral fellowship at Harvard University. She is an ISCB Fellow and has received the Burroughs Wellcome Fund Career Award, NSF CAREER award, Stand Up To Cancer Innovative Research Grant, NIH Director's New Innovator and Pioneer awards, Packard Fellowship in Science and Engineering, Ernst W. Bertner Memorial Award and ISCB Overton Prize. She serves on the editorial board of Cell, leads the MSK Center within the NCI Human Tumor Atlas Network, and heads computational analysis for the Human Cell Atlas project, where she is also an active Organizing Committee member. Dr. Pe'er is a Howard Hughes Medical Institute investigator.



Reena Philip, PhD

Oncology Center of Excellence, Food and Drug Administration

Reena Philip, PhD, currently holds the position of Associate Director, Biomarkers and Precision Oncology in Oncology Center of Excellence (OCE), FDA. Prior to this, Dr. Philip was the Director of the Division of Molecular Genetics and Pathology, at Center for Devices and Radiologic Health at the FDA for almost 9 years. At the FDA, she leads OCE's efforts surrounding cancer biomarkers and diagnostics both internally and for external outreach and collaboration. She works on policy and guidance on tumor biomarkers and diagnostics, providing advice, consultation, and assistance on precision oncology matters to the other Centers

in the Agency. Prior to joining the FDA, Dr. Philip's experience included 3 years in the US biotechnology industry. Dr. Philip received her PhD from University of Illinois at Urbana-Champaign.



Kimryn Rathmell, MD, PhD

Vanderbilt University Medical Center

Kimryn Rathmell, MD, PhD, is the Hugh Jackson Morgan Professor and Chair of Medicine at Vanderbilt University Medical Center (VUMC), and Physician-in-Chief for Vanderbilt University Adult Hospital and Clinics.

Rathmell earned her PhD in biophysics and MD from Stanford University. Following completion of her MD, she did an Internal Medicine internship at the University of Chicago before attending the University of Pennsylvania where she completed an Internal Medicine residency and Medical Oncology fellowship. She completed postdoctoral training at the University of Pennsylvania, working with Dr. Celeste Simon. A physician-scientist, Rathmell's work focuses on the treatment and research of complex renal cell carcinomas. Her research has resulted in over 20 years of funding from the National Institutes of Health, and more than 200 articles in leading peer-reviewed journals,

including *The New England Journal of Medicine*, *Nature*, and the *Journal of Clinical Investigation (JCI)*. In 2015, Rathmell joined VUMC as Professor of Medicine and Director of the Division of Hematology and Oncology, with a secondary appointment in the Department of Biochemistry. In 2019, she was named Deputy Director for Research Integration and Career Development at Vanderbilt-Ingram Cancer Center. She served in this role until her appointment as Chair of the Department of Medicine in 2020. Prior to Vanderbilt, Rathmell served on faculty at the University of North Carolina at Chapel Hill (UNC) where she was co-director of the Howard Hughes Medical Institute Graduate Training Program in Translational Medicine, Associate Director for Training and Education at UNC Lineberger Comprehensive Cancer Center, and Associate Director and Alexander Family Chair in Translational Research for the Medical Scientist Training Program. She is a member of The Cancer Genome Atlas, winning the American Association for Cancer Research Team Science Award in 2021, and serves on the National Cancer Institute's Board of Scientific Advisors and on the Forbeck Foundation Scientific Board of Directors. She is a senior editor for *eLIFE*, and has served on editorial boards for *JCI*, *Kidney Cancer*, and *JCO-Precision Oncology*. She has held leadership positions for the American Society of Clinical Oncology, Kidney Cancer Research Foundation, and the American Society for Clinical Investigation (ASCI), serving as the Secretary-Treasurer, and later President of that organization. As a result of her contributions, Rathmell has been elected to the ASCI, the Association of American Physicians, the American Clinical and Climatological Society, and as a fellow of the American Association for the Advancement of Science.



Elad Sharon, MD, MPH

National Cancer Institute Cancer Therapy Evaluation Program

Elad Sharon, MD, MPH, joined the NCI Cancer Therapy Evaluation Program (CTEP) in December 2011 as a Medical Officer in the Investigational Drug Branch, where he works with academia and industry to develop promising new cancer therapies. His portfolio includes antibody-drug conjugates, immune checkpoint inhibitors and other agents. Dr. Sharon co-directs immunotherapy trials at CTEP and serves as an attending physician in NCI's Developmental Therapeutics Clinic. As part of his work in immunotherapy drug development, he has made a major effort to advance the understanding of immune-related adverse events, including the establishment of the Alliance-NIH irAE Biorepository. In addition, Dr. Sharon is the co-Principal Investigator of the AIM-NIVO trial, evaluating the use of nivolumab for patients with pre-existing autoimmune disease. With the advent of

Cancer Moonshot, Dr. Sharon has served as the co-chair of the Adult Immunotherapy Implementation Team to help the NCI accelerate cancer care innovation.

Dr. Sharon is on program committees for several major oncology meetings. He has chaired the NIH-AACR Joint Conference on Cancer, Autoimmunity, and Immunology. He has also served on the committee and chaired several ASCO pre-annual meeting seminars on the Economics of Cancer Care. Dr. Sharon works on patterns of care projects with NCI's Healthcare Delivery Research Program using SEER data and with NCI's Surveillance Research Program to evaluate emerging practice patterns. He has worked with several providers of data to evaluate real world evidence for use in drug development and patient safety analyses, through collaborations with FDA, Friends of Cancer Research, and other stakeholders in the field.

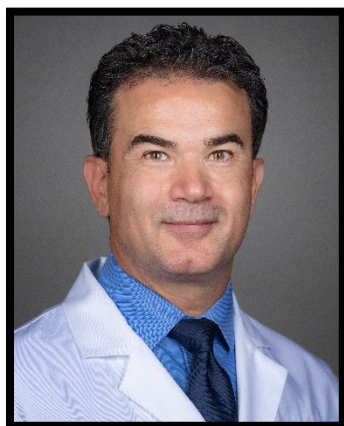
Dr. Sharon received his MD from Baylor College of Medicine in Houston, Texas, in 2003. He completed his internal medicine residency at Emory University in 2006 and his Hematology/Oncology Fellowship at NIH in 2011, while obtaining a Master of Public Health degree at the Harvard University in 2009. His fellowship research focused on clinical trials in mesothelioma. Before his fellowship at NCI, he had previously worked as a guest at the Brookings Institution. He serves as an associate editor of JNCI Cancer Spectrum and on the editorial board of JCO Clinical Cancer Informatics.



Alexandra Snyder, MD

Generate Biomedicines

Alex Snyder, MD, is the Chief Medical Officer of Generate Biomedicines, a biotechnology company that uses machine learning and biological engineering to create novel medicines. Prior to joining Generate in 2022, Dr. Snyder was a Principal at the biotech incubator Two River, following her role as Associate Vice President and Head of Translational Oncology at Merck. She previously was Translational Medicine Lead at Adaptive Biotechnologies and started her career as faculty and federally-funded Principal Investigator at Memorial Sloan Kettering Cancer Center. Dr. Snyder is a member of the Foundation for the NIH Biomarker Working group and co-leads the SITC Biomarker Working Group. She is a Clinical Assistant Professor of Medicine at NYU and Bellevue Hospitals, Section Editor for the Journal for the Immunotherapy of Cancer, and a member of the board of Navigating Cancer. Dr. Snyder received her medical degree and internal medicine training at the Icahn School of Medicine at Mount Sinai and Mount Sinai Hospital, followed by medical oncology fellowship at Memorial Sloan Kettering Cancer Center (MSKCC).



Ahmad A. Tarhini, MD, PhD

H. Lee Moffitt Cancer Center and Research Institute

Ahmad Tarhini, MD, PhD, is a senior member in the departments of Cutaneous Oncology and Immunology at H. Lee Moffitt Cancer Center and Research Institute in Tampa, FL. He serves as the Director of Cutaneous Clinical and Translational Research and is the Leader of the Cutaneous Adjuvant and Neoadjuvant Translational Science Program. Dr Tarhini is Professor of Oncologic Sciences at the University Of South Florida Morsani College Of Medicine in Tampa, FL. He received his PhD in clinical and translational science from the University Of Pittsburgh School Of Medicine and the Clinical and Translational Science Institute. Dr Tarhini is board certified in medical oncology. Throughout his career, Dr Tarhini has led multiple novel investigator-initiated clinical and translational studies, national US Cooperative Group studies, and NIH-funded translational projects investigating biomarkers of disease prognosis, immunotherapeutic benefits and toxicity risks. He has been actively involved in immune modulator therapies drug development and served as the principal investigator of the ETCTN grant at Case Comprehensive Cancer Center. Currently, Dr Tarhini serves as a chair/co-chair for several U.S. cooperative group trials, including U.S. Intergroup Clinical Trials E1609, S1404, EA6141, E3612, E3611, NCI8628, NCI10061 and EA6194. He is a recipient of the prestigious Eastern Cooperative Oncology Group Young Investigator Award and the H. Lee Moffitt Cancer Center and Research Institute Top Publication Award. He serves as the Chair of the Scientific Committee and ImmunoOncology Research Subcommittee of the Oncology

Research Information Exchange Network (ORIEN) where he leads a Team Science Award investigating predictors of immunotherapeutic benefits and risks and the mechanisms of immune resistance in patients with advanced malignancies treated with immune modulator therapies drug.



Hussein Tawbi, MD, PhD

University of Texas MD Anderson Cancer Center

Hussein Tawbi, MD, PhD, is Professor of Medical Oncology, Investigational Cancer Therapeutics, and Director of Melanoma Clinical Research and Early Drug Development at the Department of Melanoma Medical Oncology at the University of Texas MD Anderson Cancer Center. Dr. Tawbi joined MD Anderson in 2015 and in addition to being a melanoma clinician, he develops and conducts multiple clinical trials with translational endpoints in melanoma, sarcoma, and immunotherapy. His role at MD

Anderson includes providing the vision and direction of clinical translational research at the Department of Melanoma Medical Oncology and enhance the operations of the clinical research staff.

Dr. Tawbi obtained his MD in 2001 from the American University of Beirut, Beirut, Lebanon. Dr. Tawbi completed his training in Internal Medicine and Hematology/Oncology at the University of Pittsburgh and joined the faculty ranks at the University of Pittsburgh as an Assistant Professor in 2007 and was promoted to Associate Professor in 2014. His clinical training was coupled with formal instruction in Clinical and Translational Research that culminated in a PhD degree in Clinical and Translational Science in 2011. Dr. Tawbi joined the University of Texas MD Anderson Cancer Center as Associate Professor in the Departments of Melanoma Medical Oncology and Investigational Cancer Therapeutics in November 2015, and recently appointed Director of Melanoma Clinical Research and Early Drug Development. The primary focus of his research has been early phase studies of novel agents in melanoma and sarcoma. Dr. Tawbi have designed, and conducted several Phase I and Phase II studies in both diseases. Specifically he participated in the early studies of targeted agents (vemurafenib, dabrafenib, and trametinib) and immunotherapy agents (nivolumab and pembrolizumab). He has been interested in the study of special populations including patients with organ dysfunction and patients with melanoma brain metastases. Given that patients with melanoma brain metastases have been traditionally excluded from clinical trials, Dr. Tawbi has participated, conducted and led multicenter Phase II studies dedicated to this population and have recently shown that the combination of ipilimumab and nivolumab in untreated melanoma brain metastases is safe and has a high rate of durable responses exceeding 55%.

Dr. Tawbi has over 150 publications including high impact journals such as New England Journal of Medicine, Lancet Oncology, Journal of Clinical Oncology, Science Translational Medicine, Cancer, Cancer Research, Clinical Cancer Research, among others. He is an active member of SWOG, NCI-CTEP Organ Dysfunction Working Group, the Society for Melanoma Research, the Society for the Immunotherapy of Cancer (SITC), ASCO, and AACR.



Marc Theoret

Oncology Center of Excellence, Food and Drug Administration

Dr. Marc Theoret is a medical oncologist and Deputy Director in the Oncology Center of Excellence (OCE), FDA, and Acting Supervisory Associate Director in the Office of Oncologic Diseases (OOD), Center for Drug Evaluation and Research, FDA. Dr. Theoret earned his medical degree from the Penn State College of Medicine. He completed internship and residency training in Internal Medicine at the Beth Israel Deaconess Medical Center in Boston, and fellowship training in Hematology and Oncology at the National Cancer Institute (NCI) in Bethesda. Prior to coming to FDA, he performed basic and translational clinical research in the Surgery Branch, NCI, to investigate novel immunotherapeutic strategies to treat

patients with melanoma and other advanced solid tumors.

In 2009, Dr. Theoret came to FDA and served as a medical officer in the Division of Biologic Oncology Products and then in the Division of Oncology Products (DOP) 2. He served as the Clinical Team Leader of the Melanoma-Sarcoma team, DOP2, from 2013 to 2017. Subsequently, he served as Associate Director of Immunotherapeutics in the Office of Hematology and Oncology Products (OHOP) as well as an Acting Associate Director of Immuno-oncology Therapeutics in the Oncology Center of Excellence. Prior to his current position as Deputy Director of the OCE, he served as the Acting Deputy Office Director in OOD. In these roles in OHOP / OOD and OCE, Dr. Theoret has led the reviews of numerous breakthrough therapies, new molecular entities, and novel biologics. Dr. Theoret has contributed extensively to initiatives—regulatory, scientific, and policy efforts—in cancer therapeutic development, in particular immuno-oncology therapeutics, and consistently has provided FDA leadership in this field to wide-ranging external stakeholders.



Suzanne L. Topalian, MD

Johns Hopkins University

Suzanne L. Topalian, MD, is a physician-scientist whose studies of anti-tumor immunity have been foundational in developing cancer immunotherapy. She has published over 160 original research articles and reviews in this area and is one of the most highly cited researchers in the biomedical field. She received her medical and scientific training at Tufts University School of Medicine, Thomas Jefferson University Hospital, Children's Hospital of Philadelphia, and the National Cancer Institute. She joined the Johns Hopkins Kimmel Cancer Center in 2006 as the inaugural director of its Melanoma/Skin Cancer Program. Her current research focuses on manipulating "immune checkpoints" such as PD-1 in cancer

therapy, discovering biomarkers predicting response and resistance, and developing new strategies such as neoadjuvant (pre-surgical) anti-PD-1 administration and effective treatment combinations. Dr. Topalian's work is widely recognized: she was named one of *Nature's 10* in 2014, and received the Karnofsky Award from ASCO in 2015, the Taubman Prize in 2016, the NCI's Rosalind E. Franklin Award in 2018, the American Academy of Dermatology's Gruber Memorial Cancer Research Award in 2020, and the Award for Distinguished Research in the Biomedical Sciences from the Association of American Medical Colleges in 2021, for landmark discoveries in cancer immunotherapy. Dr. Topalian was elected to the National Academy of Medicine in 2017, and she is a Fellow of the AACR Academy and SITC's Academy for Immunology. Her work has opened new avenues of scientific investigation and has established immunotherapy as a pillar of oncology.



George J. Weiner, MD

University of Iowa and Holden Comprehensive Cancer Center

George J. Weiner, MD, is the C.E. Block Chair of Cancer Research and Professor of Internal Medicine at the University of Iowa. He has also served as the Director of the Holden Comprehensive Cancer Center at the University of Iowa for the past 22 years. He has an active translational cancer immunotherapy research program that has been continually funded by the NCI for over 30 years. Dr. Weiner is a Past President of the Association of American Cancer Institutes.

Dr. Weiner obtained his undergraduate education from Johns Hopkins University, his medical degree at The Ohio State University, his Internal Medicine Training at the Medical College of Ohio and his Oncology and Hematology training at The University of Michigan where he also trained in tumor immunology. He has been a faculty member at the University of Iowa since 1989. Dr. Weiner is board certified in Internal Medicine, Hematology and Medical Oncology.



Jedd Wolchok, MD, PhD, FASCO

Weill Cornell Medicine

Jedd Wolchok, MD, PhD, FASCO, is the Meyer Director of the Sandra and Edward Meyer Cancer Center and Professor of Medicine at Weill Cornell Medicine. Dr. Wolchok is a clinician-scientist exploring innovative immunotherapeutic strategies in laboratory models, and a principal investigator in numerous pivotal clinical trials. Dr. Wolchok helped establish immunotherapy as a standard approach to cancer treatment and was instrumental in the clinical development leading to the approval of ipilimumab and the combination of nivolumab and ipilimumab for advanced melanoma. He supervises an NIH R01-

funded basic science laboratory that is focused on investigating novel immunotherapeutic agents in pre-clinical laboratory models. The focus of his translational research laboratory is to investigate innovative means to modulate the immune response to cancer as well as to better understand the mechanistic basis for sensitivity and resistance to currently available immunotherapies.



Prakirthi Yerram, PharmD, BCOP
Flatiron Health

Prakirthi Yerram, PharmD, BCOP, is a Board Certified Oncology Pharmacist working as a Clinical Director of Research Oncology, Real World Evidence at Flatiron Health. In her current role, Dr. Yerram works on how to optimize the capture of adverse events in real world data. Prior to joining Flatiron, Dr. Yerram worked at Memorial Sloan Kettering as a Neuro-Oncology Clinical Pharmacy Specialist. She completed her Doctor of Pharmacy from Ernest Mario School of Pharmacy at Rutgers University in New Brunswick, NJ. She completed her PGY1 Pharmacy Practice Residency at Yale- New Haven Hospital in New Haven, CT and her PGY2 Hematology/Oncology Pharmacy Residency at Duke University Hospital in Durham, NC.



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.

nationalacademies.org/NCPF

To receive updates on the National
Cancer Policy Forum, visit

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Medicine

Upcoming and Recent Workshops

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 dramatically reshape cancer diagnosis and enable precision therapy. Spurred by advances in informatics, there are opportunities to combine and collate 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 for improved patient outcomes. Integrated diagnostics also have the potential to improve patient access to subspecialty expertise, particularly in community-based settings of cancer care. A National Academies workshop could help the cancer community better define the purpose, goals, and components of integrated diagnostics and provide a venue to discuss policy, research, technical, and workforce considerations to help realize the potential of integrated diagnostics.

Workshop website in development

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

Advances in immunotherapy research and development have ushered in a new era for cancer treatment, resulting in improved treatment options and outcomes for people living with and beyond cancer. Although immunotherapy has shown to be effective in improving patient outcomes in some contexts, patient responses to immunotherapy treatment can vary widely, and many patients who initially respond to 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 is an opportunity for participants in the cancer research and care community to examine the current challenges related to resistance to immunotherapies and to discuss potential policy options that could help overcome these challenges.

[Workshop website](#)



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 website](#)

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](#)

Innovation in Electronic Health Records for Oncology Care, Research, and Surveillance

Collaborative workshop convened by:

National Cancer Policy Forum
Computer Science and Telecommunications Board

February 28-March 1, 2022

The workshop reviewed the history and current status of electronic health records (EHRs), strategies to optimize EHR functionality and usability, as well as opportunities for collaboration and innovation in the development, implementation, and use of EHRs to improve oncology care, research, and surveillance.

[Workshop videos and presentations](#)

Recent Workshops

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

December 1-3, 2021

Companion animals have a potential role as sentinels of relevant, shared environmental exposures that may affect human aging and cancer. This workshop examined the opportunities and challenges for using this novel translational approach to exposure science as a way to accelerate the knowledge turn in this evolving field.

[Workshop videos and presentations](#)

[Poster session](#)

[Proceedings](#)

[Highlights](#)

Promoting Health Equity in Cancer Care

October 25-26, 2021

Significant advancements in the delivery of high-quality cancer care and improvements in patient outcomes have been achieved in recent years; however, such progress has not been evenly distributed across the U.S. population. The Forum, in collaboration with the Roundtable on the Promotion of Health Equity, convened a workshop to examine opportunities to improve health equity for patients with cancer.

[Workshop videos and presentations](#)

[Proceedings](#)

Webinar Series: Addressing Social Needs in Cancer Care

In advance of the workshop, *Promoting Health Equity in Cancer Care*, the Forum convened a webinar series focusing on opportunities to better assess and address the social needs of patients with cancer.

- May 10, 2021: [Food Insecurity among Patients with Cancer](#)
- August 9, 2021: [Housing Insecurity among Patients with Cancer](#)
- September 21, 2021: [Transportation Needs among Patients with Cancer](#)

Innovation in Cancer Care and Cancer Research in the Context of the COVID-19 Pandemic

July 26-27, 2021

The COVID-19 pandemic has led to dramatic adjustments in cancer care delivery and cancer research. This workshop examined these changes, and considered lessons learned in order to improve the delivery of high-quality cancer care and the conduct of cancer clinical trials in the post-pandemic era. Participants identified potential policy opportunities to retain and build on the beneficial changes that occurred during the pandemic.

[Workshop videos and presentations](#)

[Proceedings](#)

Impact of the Affordable Care Act on Cancer Prevention and Cancer Care

March 1-2, 2021

The Forum convened this workshop to examine the evidence base on how the Patient Protection and Affordable Care Act (ACA) has altered the landscape of cancer prevention and care delivery. Workshop presentations and discussions reviewed the effects of the ACA on people at risk for or living with cancer and provided insight into remaining policy challenges that could inform future efforts to improve the delivery of high-quality cancer care across the care continuum.

[Workshop videos and presentations](#)

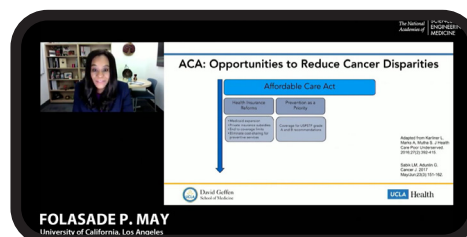
[Proceedings](#)

[Reels](#)

[Interactive overview](#)



Still from the workshop [reel](#): Opportunities for Action: Strengthening Patient, Clinician, and Community Engagement



Still from the workshop [reel](#): Improving Access to High-Quality Prevention and Care



Still from the workshop [reel](#): Addressing the Social Determinants of Health to Address Health Equity

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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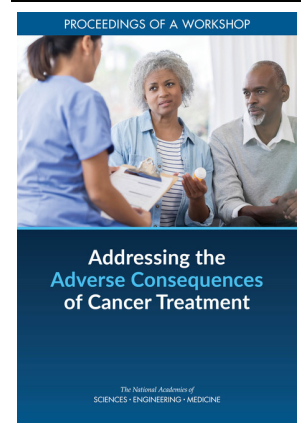
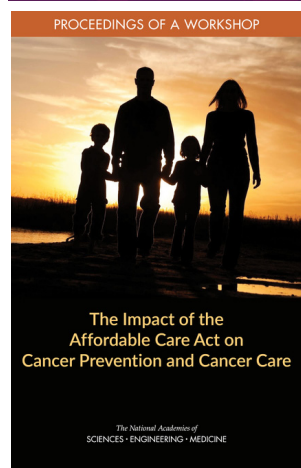
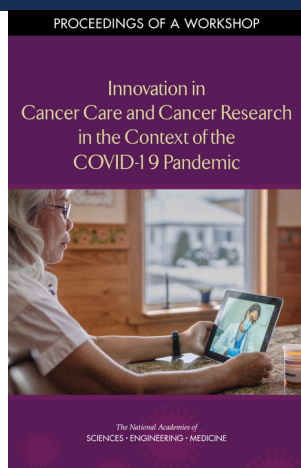
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NATIONAL CANCER POLICY FORUM

WORKSHOP PROCEEDINGS AND RELATED PUBLICATIONS



WORKSHOP PROCEEDINGS

2022

Advancing Progress in Cancer Prevention and Risk Reduction (In Process)
Family Caregiving for People with Cancer and Other Serious Illnesses (In Process)
Innovation in Electronic Health Records for Cancer Care, Research, and Surveillance: A Workshop (In Process)
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

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

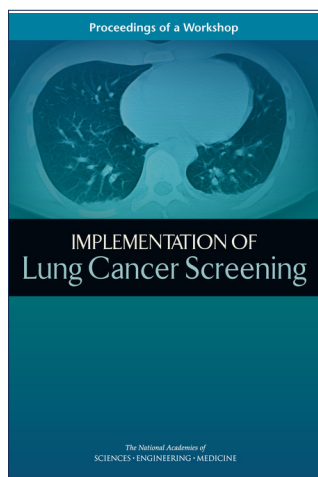
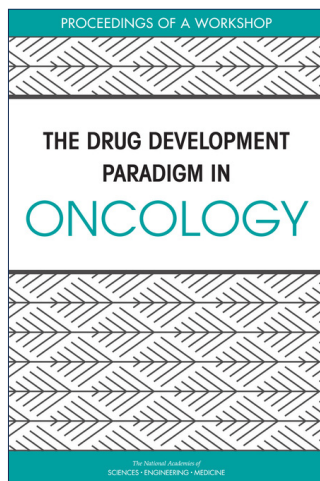
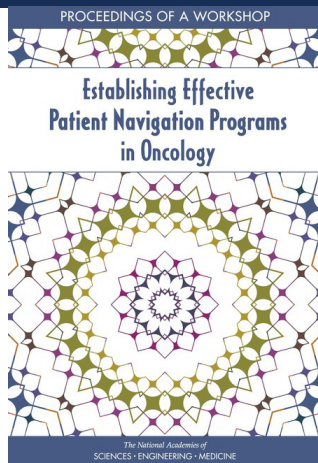
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Sciences
Engineering
Medicine



WORKSHOP PROCEEDINGS

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

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

IMPLEMENTING A NATIONAL CANCER CLINICAL TRIALS SYSTEM FOR THE 21ST CENTURY

Workshop Summary



WORKSHOP PROCEEDINGS

2011, continued

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

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

EXTENDING THE SPECTRUM OF PRECOMPETITIVE COLLABORATION IN ONCOLOGY RESEARCH

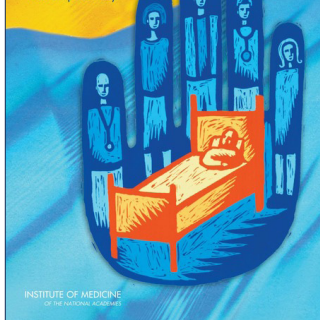
WORKSHOP SUMMARY



INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

ASSESSING AND IMPROVING VALUE IN CANCER CARE

Workshop Summary



INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Implementing COLORECTAL CANCER Screening

WORKSHOP SUMMARY



INSTITUTE OF MEDICINE
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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)

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Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease (2010)

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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)

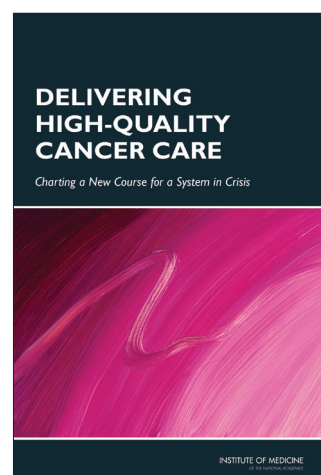
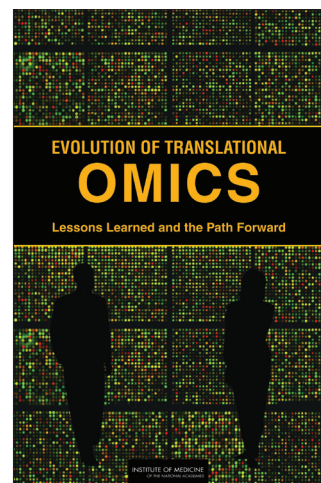
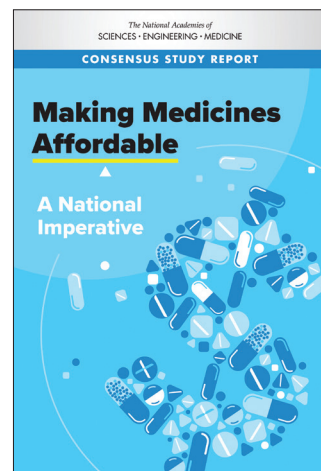
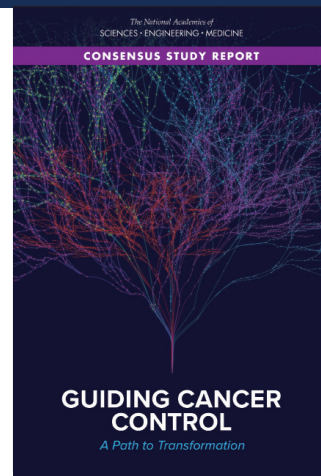
Report: nap.edu/read/11892

INDIVIDUALLY AUTHORED PUBLICATIONS BUILDING ON NCPF WORK

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

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- Bono, K. and N. L. Keating. 2022. Addressing social determinants of health: Now is the time. *Journal of the National Cancer Institute*. <https://academic.oup.com/jnci/advance-article/doi/10.1093/jnci/djac137/6705076?searchresult=1>.
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- Nekhlyudov L., G. B. Campbell, K. H. Schmitz, G.A. Brooks, A.J. Kumar, P.A. Ganz, and D. Von Ah. 2022. Cancer-related impairments and functional limitations among long-term cancer survivors: Gaps and opportunities for clinical practice. *Cancer* 128(2): 222-229. <https://pubmed.ncbi.nlm.nih.gov/34529268/>.



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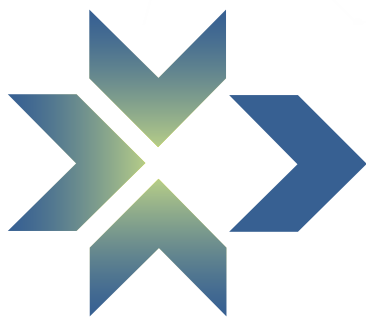
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Forum on
**DRUG DISCOVERY,
DEVELOPMENT,
and TRANSLATION**

Activities, Products, Impact

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 provide a unique platform for dialogue and collaboration among thought leaders and stakeholders in government, academia, industry, foundations, and patient advocacy with an interest in improving the system of drug discovery, development, and translation. The Forum brings together leaders from private-sector sponsors of biomedical and clinical research, federal agencies sponsoring and regulating biomedical and clinical research, the academic community, and patients, and in doing so serves to educate the policy community about issues where science and policy intersect.

The Forum convenes a few times each year to identify and discuss key problems and strategies in the discovery, development, and translation of drugs. To supplement the perspectives and expertise of its members, the Forum also holds public workshops to engage a wide range of experts, members of the public, and the policy community. The Forum also fosters collaborations among its members and constituencies.

For more information about the Forum on Drug Discovery, Development, and Translation, please visit www.nationalacademies.org/DrugForum.





FORUM THEMES AND PRIORITIES

Innovation and the Drug Research and Development Enterprise

Despite exciting scientific advances, the path from basic science to new therapeutics faces challenges on many fronts. Innovative paradigms are needed to bridge the ever-widening gap between scientific discoveries and the translation of those discoveries into life-changing medications. There is increasing recognition of the need for new models and methodologies to advance drug discovery, development, and translational science. The Forum serves as a hub and a catalyst for nurturing new ideas, collaborations, and partnerships and offers a neutral space for stakeholders to help chart a course through the turbulent forces of disruptive innovation and advance critical policy discussions on biopharmaceutical R&D nationally and globally.

Science Across the Biomedical Research Lifecycle

Revolutionary advances in biomedical research and technology applications present new and exciting opportunities for the discovery and development of new therapies for patients. At the same time, key gaps remain in our knowledge about the science, technology, and methodologies needed to support the research that underpins drug discovery and development. The Forum provides a neutral venue to focus attention on key scientific issues across the biomedical research lifecycle and facilitate the exploration of new and more patient-centric approaches to spur innovation. The Forum continues to support activities that contribute toward the defining, establishment, and refinement of biomedical and regulatory science and other critical aspects of drug discovery and medical product development.

Clinical Trials and Medical Product Development

Clinical research provides a critical link between the laboratory bench and patients' bedside when it comes to developing new therapeutics and advancing understanding of health maintenance and prevention and disease progression. However, the clinical research enterprise faces continued and mounting pressures, strained from all sides by rising costs, an evolving regulatory and economic landscape, increasing clinical trial complexity, difficulties in the recruitment and retention of research participants, and a clinical research workforce that is under tremendous stress. Collaborative, cross-sector approaches that engage patients, providers, academia, industry, federal agencies, payers, nonprofit organizations, and funders can help to effectively address the key challenges and to develop systems-based solutions.

Infrastructure and Workforce for Advancing Drug Discovery, Development, and Translation

Considerable opportunities remain for the improvement and enhancement of the infrastructure—the organizational framework, systems, workforce, and other resources—that supports the drug discovery and development enterprise. The fields of drug discovery and development, clinical research, and clinical practice are intersecting, cross-cutting, and multidisciplinary. However, career paths in these fields are difficult to pursue, training may be lacking, and career opportunities may be limited. The Forum has considered workforce needs as foundational for the advancement of drug discovery, development, and translation and has focused substantial attention on these issues and fostered the development of strategies to improve the discipline of innovative regulatory science through the development of a robust workforce.



STRATEGIES



Facilitate visibility and continuous discussion on important issues



Foster collaboration on topics where there is synergy among potential partners



Explore innovative and transformative approaches for resolving problem areas



Educate and elevate understanding of issues



Clarify and expand areas of agreement

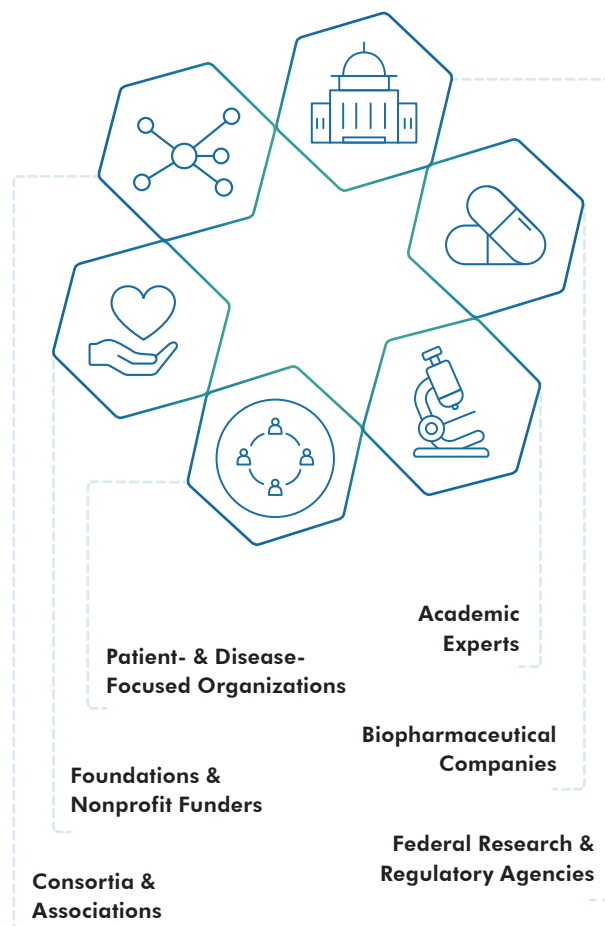


Set the stage for future policy action

Topics addressed by the Forum span a broad range of issues in drug discovery, development, policy, and practice. In providing a venue for independent, systematic discussions of these issues, the Forum employs the above strategies.



MEMBERS



The Forum has approximately 30-35 members, identified for their professional and expert perspective as well as their technical and/or public policy credentials. Expertise includes basic and clinical biomedical research, therapeutics development, health administration and policy, and patient/disease advocacy. Additional experts are invited to participate in particular Forum discussions and other activities on an ad hoc basis.



ACTIVITIES

Members of the Forum convene several times each year to identify, discuss, and act on key problems and strategies in the discovery, development, and translation of drugs. To supplement the perspectives and expertise of its members, the Forum holds public workshops to focus substantial public attention on critical areas of scientific and policy interest. The Forum also fosters action-oriented collaboratives that engage a wide range of experts, the policy community, and members of the public in an informal, neutral setting.

Forum Meetings

Building on priorities identified by Forum members during the course of Forum meetings, the Forum membership envisions future workshops and collaborative activities.



Workshops

Activity Goals

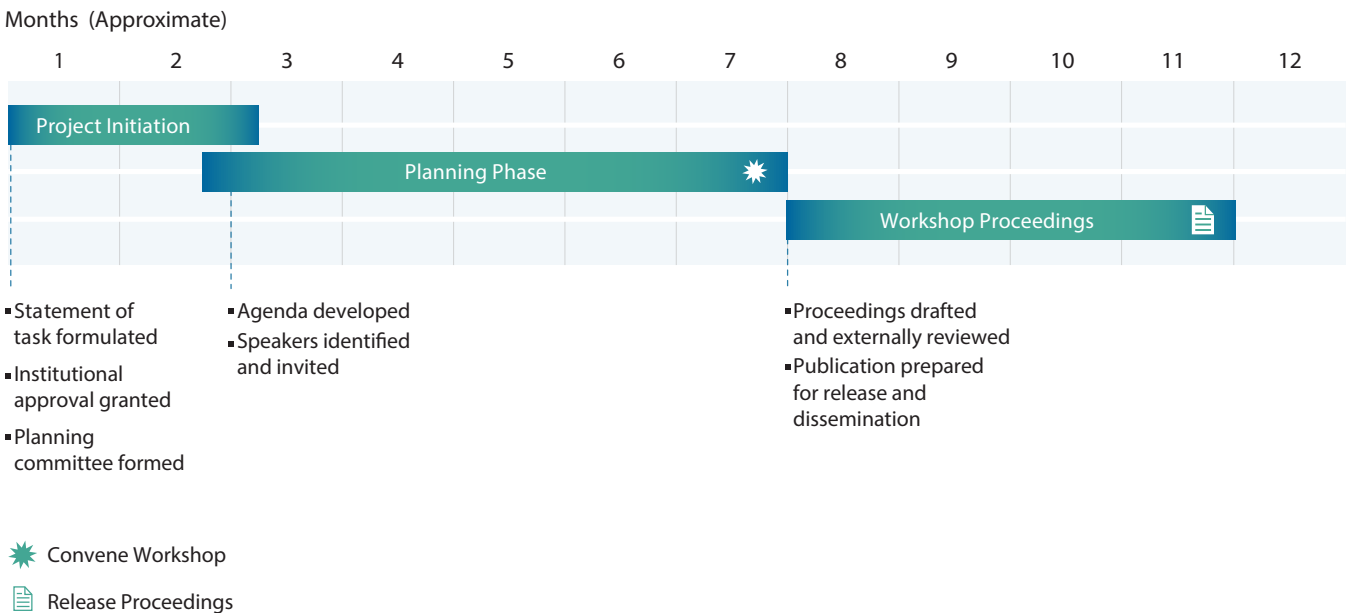
Public workshops convene experts, thought leaders, stakeholders, and members of the public from across the drug R&D and regulatory ecosystem to report on the current knowledge in an area, highlight and elucidate problems, focus substantial public attention on critical areas of scientific and policy interest, or discuss the progress of policy change following the release of a National Academies consensus study report.

Process

Workshops are organized by planning committees, which may include Forum members. Over the course of five to six months, the planning committee convenes to scope and plan the workshop (see the figure below). Forum staff facilitate convening the planning committee and promoting the workshop to relevant stakeholders and the public. Workshops typically result in the publication of a workshop proceedings (find out more under “Products”).

Outcomes

Workshop proceedings are published to communicate the information and dialogue presented at the workshop to a wider audience. Workshops may result in the formation of action collaboratives, follow-on discussion papers or commentaries, a workshop series, or spin-off consensus studies.



Action Collaboratives

Activity Goals

The Forum fosters action collaboratives to engage participants with similar interests and responsibilities in cooperative activities that analyze in-depth high-priority issues and advance identified goals of the Forum and progress on recommendations highlighted in previous National Academies consensus reports. Collaboratives are participant-driven, action-oriented activities that foster collaboration and information sharing among Forum members and external thought leaders and stakeholders. Collaboratives may:

- identify issues of common interest and marshal needed leadership, expertise, and resources;
- highlight potential paths forward through, e.g., individually authored (or small group) literature summaries or discussion papers or through the convening of technical discussions;
- engage in cooperative development of tools needed for progress;
- incubate and pilot-test novel approaches; and
- develop proposals for formal workshops and studies for consideration by the National Academies.

Each action collaborative is an ad hoc activity associated with the Forum at the National Academies. The work it produces does not necessarily represent the views of any one organization, the Forum, or the National Academies and has not been subjected to the review procedures of, nor is it a report or product of, the National Academies.

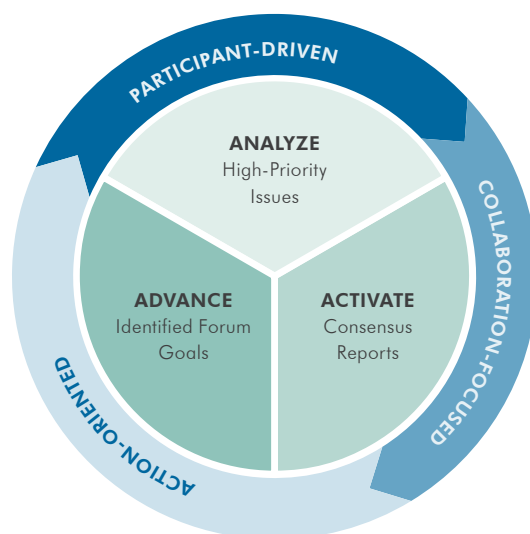
Process

Collaboratives meet under the auspices of the Forum. They vary in structure and content to meet the specified needs and challenges identified by their participants. Collaborative participants and their colleagues often provide in-kind support (such as human resources) to further the Collaborative's goals, with support and facilitation by Forum staff. The timeline and frequency with which Collaboratives meet is determined by its participants; however, many Collaboratives meet for an average of 1.5–2 years, hold regular teleconferences, and meet in person several times.

Impact/Reach

Collaboratives offer considerable flexibility for their participants to pursue a wide range of activities and products and the opportunity to have an impact on the field. Products are ascribed to the Collaborative participants and are not products of the National Academies, and endorsement and use of the Collaborative's work is at the discretion of its participants' individual organizations. Examples of impact/reach might include:

- advancing progress on recommendations highlighted in previous National Academies reports;
- developing papers authored by individual participants in the Collaborative;
- submitting journal articles to independent publications;
- spurring formation of public–private partnerships; and
- envisioning a charge for a planning committee to convene a workshop or a consensus study.





PRODUCTS

Workshop Proceedings

Workshops often result in a Proceedings of a Workshop (or Proceedings of a Workshop-in Brief). A workshop proceedings is written by National Academies staff and/or hired consultants, serving as rapporteurs, as a direct account of the workshop discussions and dialogue by workshop participants and members of the Forum. Members of the Forum and of the planning committee may not serve as rapporteurs. A workshop proceedings is reviewed by a diverse range of experts, which may include Forum members.

Perspectives: Discussion Papers and Commentaries

Authored discussion papers and commentaries (collectively termed Perspectives) can disseminate information or further elucidate topics covered in Forum discussions, workshops, or action collaboratives. Perspectives, published by the National Academy of Medicine (NAM), are individually authored by Roundtable and Forum members and outside experts in health and health care. The views expressed in these papers are those of the authors and not necessarily of the authors' organizations, the NAM, or the National Academies of Sciences, Engineering, and Medicine (the National Academies). Perspectives are intended to help inform and stimulate discussion. They are not reports of the NAM or the National Academies.

Independent Journal Articles and Other Publications

The Forum may commission or foster the development of papers to undertake new research, as well as synthesize existing literature and explore scientific and policy issues on selected topics, through the publication of journal articles in independent publications or consultant-developed documents.



IMPACT

Influence Policies and Programs

Forum activities can inform policy and legislation; programmatic planning, direction, and budgets; educational initiatives, such as curricula and training programs; and other activities.

Foster Relationships and Collaborations

By bringing together a diverse group of stakeholders around particular topics, the Forum fosters new professional relationships, facilitates cross-sector collaborations, and enables professional development and networking, including the cultivation of new leaders.

Inspire New Ideas and Shape the Field

The dialogue and ideas generated through Forum activities and captured in related products encourages the open sharing of diverse perspectives and the interchange of ideas among multidisciplinary stakeholders. The Forum can advance and shape the field by framing issues and shining a light on important topics, and by generating novel approaches to overcome existing challenges, spurring progress and inspiring action.

Incorporating Integrated Diagnostics into Precision Oncology Care: A Workshop

March 6-7, 2023

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

Collaborative National Academies Workshop

National Cancer Policy Forum
Computer Science and Telecommunications Board
Board on Human-Systems Integration

Statement of Task

A planning committee of the National Academies of Sciences, Engineering, and Medicine will plan and host a 1.5-day public workshop that will examine the state of the science and the vision for integrated diagnostics in precision oncology care. The workshop will feature invited presentations and panel discussions on topics that may include:

- Current efforts to develop and implement integrated diagnostics to inform treatment decision making in cancer care.
- Implications of integrated diagnostics for clinician training, care workflows, and organization of care teams.
- Opportunities for evidence generation to inform validation, clinical utility, oversight, as well as coverage and reimbursement for integrated diagnostics.
- Strategies for ongoing quality assurance, evaluation, and refinement of integrated cancer diagnostics based on new evidence.
- Mechanisms to enable broad patient access to integrated diagnostics, particularly in community-based settings of cancer care.

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:

Kojo S. J. Elenitoba-Johnson (*Co-Chair*), Memorial Sloan Kettering Cancer Center
Hedvig (Hedi) Hricak (*Co-Chair*), Memorial Sloan Kettering Cancer Center
Christina Chapman, Baylor College of Medicine
Nancy E. Davidson, Fred Hutchinson Cancer Center and Seattle Cancer Care Alliance
Scot W. Ebbinghaus, Merck Research Laboratories
Roy A. Jensen, The University of Kansas Cancer Center
Beth Y. Karlan, University of California, Los Angeles
Mia Levy, Foundation Medicine, Inc.
Aanand D. Naik, UTHealth Houston
Wendy Nilsen, National Science Foundation
Jason M. Slagle, Vanderbilt University Medical Center

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Arzoo Tayyeb, Finance Business Partner
Erin Balogh, Senior Program Officer; Co-Director, National Cancer Policy Forum
Sharyl Nass, Senior Director, Board on Health Care Services; Co-Director, National Cancer Policy Forum

Website Pending

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

April 2023

Statement of Task:

A planning committee of the National Academies of Sciences, Engineering, and Medicine will plan and host a 1-day public workshop to explore the state of the science with regard to the identification of genomic and epigenomic biomarkers of environmental exposures associated with cancers, with emphasis on pediatric cancers. The workshop would provide background information to assist the Centers for Disease Control and Prevention in revising their Cancer Cluster Guidelines. The workshop will feature invited presentations and panel discussion on topics that may include:

- Technologies and methodologies for the identification and validation of genomic and epigenomic biomarkers of environmental exposures and tumorigenesis;
- Statistical, epidemiological, and geospatial methodologies to assess the association of these biomarkers with unusual cancer clusters;
- The potential use of these biomarkers to identify groupings of pediatric cancers with common genetic aberrations due to environmental exposures, in addition to the index cancer identified in a cluster;
- Strategies for communication about environmental exposures and cancer risk;
- Research gaps in the genomics and epigenomics of cancers and environmental exposures and how they could be addressed.

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.

Planning Committee and Workshop Webpage Pending

Project Staff:

Jennifer Flaubert, Program Officer

Lori Brenig, Research Associate

Chidinma Chukwurah, Senior Program Assistant

Sharyl Nass, Senior Director, Board on Health Care Services