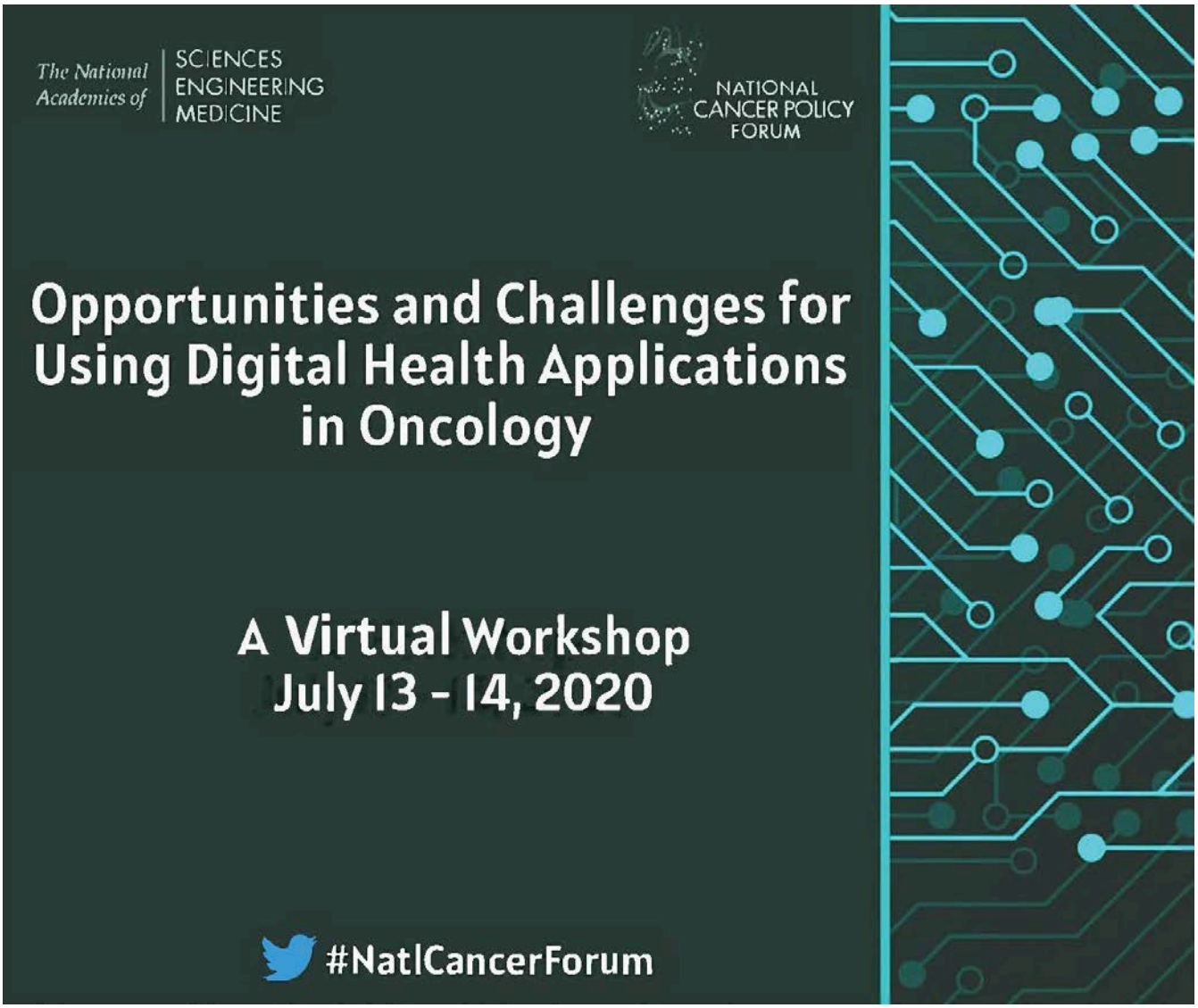
A National Cancer Policy Forum Workshop hosted in collaboration with the Forum on Cyber Resilience

Webcast: https://www.nationalacademies.org/event/07-13-2020/opportunities-and-challenges-for-using-digital-health-applications-in-oncology-a-workshop



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NATIONAL
CANCER POLICY
FORUM

NATIONAL CANCER POLICY FORUM

July 13, 2020

Dear Colleagues,

Welcome to the virtual workshop, *Opportunities and Challenges for Using Digital Health Applications in Oncology,* convened by the National Cancer Policy Forum, in collaboration with the Forum on Cyber Resilience.

We began planning for this workshop well before the COVID-19 pandemic. The intent was for workshop speakers to examine the key policy issues for the effective and safe development, implementation, and use of digital health technologies in oncology research and care. Against the backdrop of the ongoing pandemic, planning discussions evolved as we witnessed the rapid uptake of digital healthcare in our communities and across the nation. This confluence of circumstances has the potential to shape the future of oncology research and care for decades. Thus, it is even more critical to come together now to discuss the policy landscape for digital health, to make certain that we advance forward proactively to ensure the delivery of high-quality cancer care and improve patient outcomes. We should endeavor to capitalize on what we are learning during the pandemic, ensuring that we sustain and disseminate the successful aspects of research and care redesign.

The workshop will include: exemplars of novel digital health technologies, with an emphasis on patient-facing applications; regulatory, ethical, security, governance, and payment considerations; as well as discussion on the opportunities to improve data availability and use in EHRs and large databases. We will conclude the workshop with a panel discussion highlighting speaker reactions and recommendations to improve digital health-enabled oncology research and care.

We welcome your involvement in the workshop. Please use the chatbox on our website (https://www.nationalacademies.org/event/07-13-2020/opportunities-and-challenges-for-using-digital-health-applications-in-oncology-a-workshop) to ask questions, and please include 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.

Sincerely,

Lawrence N. Shulman, MD, MACP, FASCO
Planning Committee Chair
Deputy Director, Clinical Services
Director, Center for Global Cancer Medicine
Abramson Cancer Center
University of Pennsylvania

NATIONAL CANCER POLICY FORUM

Webcast Notes

- The livestream of the webcast is available at:

  https://www.nationalacademies.org/event/07-13-2020/opportunities-and-challenges-for-using-digital-health-applications-in-oncology-a-workshop

- We welcome your involvement in the workshop. Please use the chatbox on our website (located below the livestream) to ask questions, and please include your name and affiliation.
- This workshop is being webcast and recorded. The webcast and presentation files will be archived on the project webpage.
- Please use hashtag **#NatlCancerForum** to tweet about the workshop.
- Interested in receiving updates from the National Cancer Policy Forum or the National Academies of Sciences, Engineering, and Medicine's Health and Medicine Division? Sign up at:

  https://nationalacademies.us8.list-manage.com/subscribe?u=ab74d126b7d2db12591de5c2c&id=211686812e

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

NATIONAL CANCER POLICY FORUM

Opportunities and Challenges for Using Digital Health Applications in Oncology: A Virtual Workshop

WEBCAST: https://www.nationalacademies.org/event/07-13-2020/opportunities-and-challenges-for-using-digital-health-applications-in-oncology-a-workshop

AGENDA

Monday, July 13, 2020	
9:30 am	**Welcome from the National Cancer Policy Forum and Forum on Cyber Resilience** Lawrence Shulman, University of Pennsylvania Workshop Planning Committee Chair Fred Schneider, Cornell University Chair, Forum on Cyber Resilience
9:45 am	**Session 1: Overview of Digital Health Applications in Oncology** *Moderator: Lawrence Shulman, University of Pennsylvania* **Digital Health in Cancer** • Mia Levy, Rush University Medical Center **Keynote Presentation** **COVID-19 and Oncology Digital Health: FDA Perspective** • Anand Shah, Food and Drug Administration **Panel Discussion (15 minutes)**
10:30 am	**Break**
10:45 am	**Session 2: Lightning Round Presentations: Exemplars of Novel Digital Health Applications** *Moderators: Deborah Estrin, Cornell Tech and Randall Oyer, Penn Medicine Lancaster General Health* **Patient-Facing Digital Applications** • Sam Takvorian, University of Pennsylvania • Andrea Pusic, Harvard Medical School • Panel Discussion (15 minutes)

	Radiology and Pathology Digital Applications • Thomas Fuchs, Memorial Sloan Kettering Cancer Center • Sanjay Aneja, Yale University • Panel Discussion (15 minutes) **Research/EHRs/Databases** • Allison W. Kurian, Stanford University • Ravi Parikh, University of Pennsylvania • Panel Discussion (15 minutes)
12:15 pm	**Break**
1:00 pm	**Session 3A: FDA Vision and Priorities for Regulating Digital Health Applications—Q&A with Lawrence Shulman** • Amy Abernethy, Food and Drug Administration
1:35 pm	**Session 3B: Ethical, Security, Governance, and Payment Issues with Digital Health Applications in Oncology** *Moderators: Deven McGraw, Ciitizen and Bradley Malin, Vanderbilt University* **Legal Considerations - Patient Privacy and Data Security** • Kristen Rosati, Coppersmith Brockelman **Ethics and Digital Health: What is the Purpose of a Digital Health System and What Must be its Ethical Commitments?** • Nancy E. Kass, Johns Hopkins University **Data Governance and Access: International Perspective** • Yann Joly, McGill University **Race Matters in Oncology Apps** • Kadija Ferryman, New York University Tandon School of Engineering **Payment Policy: Digital Health and Access** • Cathy J. Bradley, University of Colorado Cancer Center **Panel Discussion (30 minutes)** Include speakers and • Andrea Downing, The Light Collective

2:55 pm	**Break**
3:05 pm	**Session 4: Patient-Facing Digital Technologies** *Moderator: Karen Basen-Engquist, University of Texas MD Anderson Cancer Center* **Patient Access to their Health Data, Storage, and Portability** • Anil Sethi and Deven McGraw, Ciitizen **Electronic Patient-Reported Outcomes (ePROs) as Digital Therapeutics** • Ethan Basch, University of North Carolina **Wearable, Mobile and Remote Monitoring Technologies in Oncology: Current Evidence and Future Opportunities** • Susan Peterson, University of Texas MD Anderson Cancer Center **Telehealth in Oncology: Learnings From the Rapid and Broad Implementation During COVID-19 Pandemic** • Mia Levy, Rush University **Panel Discussion (30 minutes)** • Alicyn Campbell, AstraZeneca • Dave Dubin, AliveAndKickn
4:15 pm	**Adjourn**
Tuesday, July 14, 2020	
9:00 am	**Cancer Medicine, Digital Health, and the COVID-19 Pandemic… and After…** • Lawrence Shulman, University of Pennsylvania Workshop Planning Committee Chair
9:10 am	**Session 5: Opportunities to Improve Data Availability and Usage in EHRs and Large Databases** *Moderator: Lawrence Shulman, University of Pennsylvania* **Leveraging Electronic Health Records to Narrow the Divide Between Research and Practice** • Neal Meropol, Flatiron Health **Minimal Common Oncology Data Elements (mCODE)**

	• Monica Bertagnolli, Dana-Farber Cancer Institute/Brigham and Women's Cancer Center **Utilizing Data and Machine Learning to Change Predictive Analytics into Prescriptive Analytics** • Sibel Blau, Quality Cancer Care Alliance Network **Panel Discussion (25 minutes)** Include speakers and: Brian Anderson, Mitre Corporation
10:15 am	**Break**
10:25 am	**Session 6: Panel Discussion: Participant Reactions and Recommendations for the Path Forward** *Moderator: Lisa Kennedy Sheldon, Oncology Nursing Society* **Panelists (5 minutes each for introductory remarks)** o Elisabeth Belmont, MaineHealth o Paul Kluetz, Food and Drug Administration o Mia Levy, Rush University Medical Center o Neal Meropol, Flatiron Health o Susan Peterson, MD Anderson Cancer Center o Lara Strawbridge, Centers for Medicare & Medicaid Services **Discussion (30 minutes)**
11:25 am	**Workshop Wrap Up** Lawrence Shulman, Workshop Planning Committee Chair
11:30 am	**Adjourn**

NATIONAL CANCER POLICY FORUM

WORKSHOP PLANNING COMMITTEE MEMBERS

Lawrence N. Shulman, MD, MACP, FASCO
Chair
Professor of Medicine
Deputy Director, Clinical Services
Director, Center for Global Cancer Medicine
Abramson Cancer Center
University of Pennsylvania

Karen Basen-Engquist, PhD, MPH
Annie Laurie Howard Research Distinguished Professor
Director, Center for Energy Balance in Center Prevention & Survivorship
Professor of Behavioral Science
The University of Texas MD Anderson Cancer Center

Cathy J. Bradley, Ph.D.
David F. and Margaret Turley Grohne Endowed Chair for Cancer Prevention and Control Research
Professor and Associate Dean for Research
Colorado School of Public Health
Deputy Director, University of Colorado Comprehensive Cancer Center

Deborah Estrin, PhD
Associate Dean for Impact
Robert V. Tishman '37 Professor
Computer Science Department
Cornell Tech

Lisa Kennedy Sheldon, PhD, ANP-BC, AOCNP®, FAAN
Clinical and Scientific Affairs Liaison
Oncology Nursing Society
Oncology Nurse Practitioner
St. Joseph Hospital

Mia Levy, MD, PhD
Sheba Foundation Director
Rush University Cancer Center
System Vice President, Cancer Services
Rush System for Health
Associate Professor of Medicine
Division of Hematology and Oncology
Rush University

J. Leonard Lichtenfeld, MD, MACP
Deputy Chief Medical Officer
American Cancer Society

Bradley Malin, PhD, FACMI
Professor and Vice Chair, Biomedical Informatics
Professor of Biostatistics and Computer Science
Co-Director, Center for Genetic Privacy and Identity in Common Settings
Co-Director, Health Data Science Center
Co-Director, Health Information Privacy Laboratory
Vanderbilt University Medical Center

Deven McGraw, JD, MPH, LLM
Chief Regulatory Officer
Ciitizen

Neal J. Meropol, MD
Vice President
Head of Medical and Scientific Affairs
Flatiron Health
Adjunct Professor
Case Comprehensive Cancer Center

Randall A. Oyer, MD
Medical Director, Oncology
Ann B. Barshinger Cancer Institute
Lancaster General Penn Medicine

SPEAKERS, PANELISTS, AND MODERATORS

Amy Abernethy, MD, PhD
Acting Chief Information Officer
Principal Deputy Commissioner
Office of the Commissioner
U.S. Food and Drug Administration

Brian S. Anderson, MD
Chief Digital Health Physician
Co-Principal Investigator
mCODE Standard Health Record
MITRE Corporation

Sanjay Aneja, MD
Assistant Professor of Therapeutic Radiology
Yale School of Medicine

Ethan Basch, MD, MSc
Physician-in-Chief
North Carolina Cancer Hospital
Chief, Division of Oncology
Richard M. Goldberg Distinguished Professor
Director, Cancer Outcomes Research Program
Lineberger Comprehensive Cancer Center
University of North Carolina at Chapel Hill

Karen Basen-Engquist, PhD, MPH
Annie Laurie Howard Research Distinguished Professor
Director, Center for Energy Balance in Cancer Prevention & Survivorship
Professor of Behavioral Science
The University of Texas MD Anderson Cancer Center

Elisabeth Belmont, JD
Corporate Counsel
MaineHealth

Monica Bertagnolli, MD
Richard E. Wilson Professor of Surgery
Harvard Medical School
Chief, Division of Surgical Oncology
Brigham and Women's Hospital
Dana-Farber Cancer Institute
Chair, Alliance for Clinical Trials in Oncology
Past President, American Society of Clinical Oncology
President, Alliance for Clinical Trials in Oncology Foundation

Sibel Blau, MD
President and Chief Executive Officer
Quality Cancer Care Alliance Network
Medical Director
Oncology Division
Northwest Medical Specialties
Clinical Associate Professor, Hematology Division
University of Washington

Cathy J. Bradley, PhD
David F. and Margaret Turley Grohne Endowed Chair for Cancer Prevention and Control Research
Professor and Associate Dean for Research, Colorado School of Public Health
Deputy Director, University of Colorado Cancer Center

Alicyn Campbell, MPH
Head
Digital Health Oncology R&D
AstraZeneca
Founder & Strategic Lead
Patient Relevant Evidence

Andrea Downing, BA Community Data Organizer President & Co-Founder The Light Collective	**Dave Dubin** Co-Founder AliveAndKickn
Deborah Estrin, PhD Associate Dean for Impact Robert V. Tishman '37 Professor Department of Computer Science Cornell Tech	**Kadija Ferryman, PhD** Industry Assistant Professor Ethics and Engineering NYU Tandon School of Engineering
Thomas Fuchs, DrSc Director of Computational Pathology Memorial Sloan Kettering Cancer Center Associate Professor Weill Cornell Graduate School of Medical Sciences Associate Attending	**Yann Joly, PhD, FCAHS, AdE** Co-Lead, GA4GH Regulatory and Ethics Work Stream Principal Investigator, Director Genetic Discrimination Observatory Associate Professor, Department of Human Genetics & Biomedical Ethics Unit Faculty of Medicine Research Director Centre of Genomics and Policy McGill University
Nancy E. Kass, ScD Vice Provost for Graduate and Professional Education Phoebe R. Berman Professor of Bioethics and Public Health Berman Institute of Bioethics Bloomberg School of Public Health Johns Hopkins University	**Lisa Kennedy Sheldon, PhD, ANP-BC, AOCNP®, FAAN** Clinical and Scientific Affairs Liaison Oncology Nursing Society Oncology Nurse Practitioner St. Joseph Hospital
Paul G. Kluetz, MD Deputy Director Oncology Center of Excellence U.S. Food and Drug Administration	**Allison W. Kurian, MD, MSc** Associate Professor of Medicine (Oncology) Associate Professor of Epidemiology and Population Health Director Women's Clinical Cancer Genetics Program Stanford University School of Medicine
Mia Levy, MD, PhD Sheba Foundation Director Rush University Cancer Center System Vice President, Cancer Services Rush System for Health Associate Professor of Medicine Division of Hematology and Oncology Rush University	**Bradley Malin, PhD, FACMI** Professor and Vice Chair, Biomedical Informatics Professor of Biostatistics and Computer Science Co-Director, Center for Genetic Privacy and Identity in Common Settings Co-Director, Health Data Science Center Co-Director, Health Information Privacy Laboratory Vanderbilt University Medical Center

Deven McGraw, JD, MPH, LLM Chief Regulatory Officer Ciitizen	**Neal J. Meropol, MD** Vice President Head of Medical and Scientific Affairs Flatiron Health Adjunct Professor Case Comprehensive Cancer Center
Randall A. Oyer, MD Medical Director, Oncology Ann B. Barshinger Cancer Institute Penn Medicine Lancaster General Health	**Ravi Parikh, MD, MPP** Assistant Professor, Medical Ethics and Health Policy University of Pennsylvania Staff Physician Corporal Michael J. Crescenz VA Medical Center
Susan K. Peterson, PhD, MPH Professor Department of Behavioral Science Division of Cancer Prevention and Population Sciences The University of Texas MD Anderson Cancer Center	**Andrea L. Pusic, MD, MHS, FACS, FRCSC** Chief Division of Plastic and Reconstructive Surgery Co-Director, Patient-Reported Outcomes, Value, and Experience Center Brigham and Women's Hospital
Kristen B. Rosati, JD Partner Coppersmith Brockelman, PLC	**Fred Schneider, PhD** Samuel B. Eckert Professor of Computer Science Cornell University
Anil Sethi, MS Founder Chief Executive Officer Ciitizen	**Anand Shah, MD, MPH** Deputy Commissioner for Medical and Scientific Affairs U.S. Food and Drug Administration
Lawrence N. Shulman, MD, MACP, FASCO Professor of Medicine Deputy Director for Clinical Services Director, Center for Global Cancer Medicine Abramson Cancer Center University of Pennsylvania	**Lara Strawbridge, MPH** Director, Division of Ambulatory Payment Models Patient Care Models Group Center for Medicare and Medicaid Innovation Centers for Medicare & Medicaid Services
Samuel U. Takvorian, MD, MS Instructor, Division of Hematology and Oncology University of Pennsylvania Perelman School of Medicine	

NATIONAL CANCER POLICY FORUM

SPEAKERS, PANELISTS, AND PLANNING COMMITTEE MEMBER BIOS

Amy Abernethy, MD, PhD
U.S. Food and Drug Administration

Amy P. Abernethy, M.D., Ph.D. is an oncologist and internationally recognized clinical data expert and clinical researcher. As the Principal Deputy Commissioner of Food and Drugs, Dr. Abernethy helps oversee FDA's day-to-day functioning and directs special and high-priority cross-cutting initiatives that impact the regulation of drugs, medical devices, tobacco and food. As acting Chief Information Officer, she oversees FDA's data and technical vision, and its execution. She has held multiple executive roles at Flatiron Health and was professor of medicine at Duke University School of Medicine, where she ran the Center for Learning Health Care and the Duke Cancer Care Research Program. Dr. Abernethy received her M.D. at Duke University, where she did her internal medicine residency, served as chief resident, and completed her hematology/oncology fellowship. She received her Ph.D. from Flinders University, her B.A. from the University of Pennsylvania and is boarded in palliative medicine.

Brian S. Anderson, MD
MITRE Corporation

Dr. Brian Anderson is a Harvard trained physician-scientist, digital health innovator and clinical systems engineer. Dr. Anderson became a nationally recognized expert on the use of information technology in support of emerging CDS models and the provision of safe, effective, patient-centered care while at athenahealth where he launched a new model of clinical decision support leveraging artificial intelligence. Dr. Anderson has also helped to develop and bring to market nascent technology and clinical workflows to support health system strategies around improved Patient Access. He has served on several national health information technology committees in partnership with the Office of the National Coordinator (ONC). Previously, Dr. Anderson led the Informatics Department at athenahealth where he focused his EHR product development around CDS systems.

As MITRE's Chief Digital Health Physician, Dr. Anderson helps to architect, implement, and analyze health information systems for CMS, HHS, the FDA and the VA. Dr. Anderson is also the Co-Principal Investigator of MITRE's largest internally funded R&D project, where he is leading the development of a common data model in Oncology based on FHIR, termed mCODE (minimal Common Oncology Data Elements).

Dr. Anderson trained at Massachusetts General Hospital and also practiced at Greater Lawrence Family Medicine. He received his MD with honors from Harvard Medical School, and a BA in Social Anthropology, cum laude from Harvard College. Dr. Anderson regularly speaks at conferences on topics in Digital Health, and the development of machine learning tools to help deliver improved clinical care and analytical insight. He has multiple publications on topics related to digital health, precision medicine and RWD strategies for Oncology.

Dr. Anderson has a passion for working at the intersection of technology, evidence-based medicine, predictive analytics and healthcare. Currently he lives in the greater Boston area, with his wife and 3 children.

Sanjay Aneja, MD
Yale School of Medicine

Sanjay Aneja, MD is an Assistant Professor within the Department of Therapeutic Radiology at Yale School of Medicine. Dr. Aneja is a physician scientist whose research group is focused on the application of machine learning techniques on clinical oncology. He received his medical degree from Yale School of Medicine and served as class president. During medical school he completed a research fellowship at the Department of Health and Human Services in large scale data analysis. He later completed his medicine internship at Memorial Sloan Kettering Cancer Center followed by his residency in radiation oncology at Yale-New Haven Hospital. During his residency he completed his post-doc in machine learning at the Center for Outcomes Research and Evaluation (CORE) receiving research grant from IBM Computing. He is currently a recipient of an NIH Career Development award, an NSF research grant, and an American Cancer Society research award.

Ethan Basch, MSc, MD
North Carolina Cancer Hospital
University of North Carolina

Dr. Ethan Basch is Physician-in-Chief of the North Carolina Cancer Hospital and Chief of Oncology at the University of North Carolina, where he is Distinguished Professor in Medical Oncology and Professor of Health Policy & Management. He leads a long-standing digital health research program which established that up to half of patients' symptoms go undetected during routine cancer care and in clinical trials, and that patient-reported outcome-based digital strategies substantially improve detection. His team determined that integrating electronic patient-reported symptom monitoring into oncology clinical practice improves clinical outcomes, including survival, and reduces health service utilization. His group created a system for the National Cancer Institute to collect patient-reported adverse events during cancer trials called the 'PRO-CTCAE.' Dr. Basch is involved in efforts to bring patient-reported data into comparative effectiveness research, routine care, and quality improvement. He is a member of the Board of Directors of ASCO, an Associate Editor at JAMA, and a prior member of the Board of Scientific Advisors for the NCI and the Methodology Committee of the Patient-Centered Outcomes Research Institute.

Karen Basen-Engquist, PhD, MPH
The University of Texas MD Anderson Cancer Center

Karen Basen-Engquist is a Professor of Behavioral Science, an Annie Laurie Howard Research Distinguished Professor, and Director of the Center for Energy Balance in Cancer Prevention and Survivorship at The University of Texas MD Anderson Cancer Center.

Dr. Basen-Engquist's research focuses on cancer survivors and the role of health behavior interventions in decreasing the severity of late effects, improving physical functioning, optimizing quality of life and reducing risk of chronic diseases. In addition, she studies intervention methods for behavior change and innovative real-time methods for assessing symptoms and behavior in cancer patients and survivors.

Dr. Basen-Engquist directs a program to help cancer survivors improve their physical functioning and quality of life through increased physical activity, funded by the Cancer Prevention and Research Institute of Texas.

Elisabeth Belmont, JD
MaineHealth

Elisabeth Belmont, J.D., serves as Corporate Counsel for MaineHealth, an integrated healthcare delivery network. She is responsible for a myriad of complex issues faced by an integrated delivery system on a daily basis and has a specialty concentration in health information and technology. Ms. Belmont has participated in a number of national initiatives where quality improvement, patient safety and information technology intersect including events sponsored by the DHHS Office of the National Coordinator, DHHS Office of the Inspector General, American Health Lawyers Association, American Society of Healthcare Risk Management and American Association for the Advancement of Science. Ms. Belmont is a former member of the Board on Health Care Services of the Health and Medicine Division of the National Academies of Sciences, Engineering and Medicine, and participated as a member of the National Academies' Committee on Diagnostic Error in Health Care. Additionally, she is a Past President of the American Health Lawyers Association, former Chair of the Association's Health Information & Technology Practice Group, and former Chair of the Association's Quality in Action Task Force. Ms. Belmont also was appointed co-Chair of the National Quality Forum's Health IT Patient Safety Measures Standing Committee. Ms. Belmont was named by the National Academies of Sciences, Engineering, and Medicine as a 2016 National Associate for outstanding contributions to the work of the National Academies.

Monica Bertagnolli, MD
Harvard Medical School
Dana-Farber Cancer Institute
Brigham & Women's Cancer Center

Dr. Bertagnolli is the Richard E. Wilson Professor of Surgery in the Field of Surgical Oncology at Harvard Medical School, and a member of the Gastrointestinal Cancer and Sarcoma Disease Centers at Dana-Farber/Brigham & Women's Cancer Center, where she collaborates with colleagues in medical oncology, radiation oncology, and pathology to treat cancer patients in a tertiary care setting.

Dr. Bertagnolli graduated from Princeton University, and attended medical school at the University of Utah. She trained in surgery at Brigham and Women's Hospital, and was a research fellow at the Dana Farber Cancer Institute (DF/BWCC). Dr. Bertagnolli has a background in laboratory work focusing upon understanding the role of the inflammatory response in epithelial tumor formation. From 1994-2011, she led gastrointestinal correlative science initiatives within the National Cancer Institute (NCI)-funded Cancer Cooperative Groups, where she facilitated integration of tumor-specific molecular markers of treatment outcome into nation-wide clinical cancer treatment protocols. From 2007-2018, Dr. Bertagnolli served as the Chief of the Division of Surgical Oncology at DF/BWCC. Dr. Bertagnolli has also had numerous leadership roles in multi-institutional cancer clinical research consortia, and currently serves as the Group Chair of the Alliance for Clinical Trials in Oncology, a nation-wide NCI-funded clinical trials group. She is also the Chief Executive Officer of Alliance Foundation Trials, LLC, a not-for-profit corporation that conducts international cancer clinical trials. In addition, Dr. Bertagnolli currently chairs the Board of Directors of the American Society of Clinical Oncology, a 45,000 member organization serving the needs of physicians and other clinicians who care for patients with cancer.

Sibel Blau, MD
Quality Cancer Care Alliance Network
Northwest Medical Specialties

Dr. Sibel Blau is a Medical Oncologist who has been in clinical practice since 2001 after completion of her Stem Cell fellowship at Fred Hutchinson Cancer Research Center. In addition to her work as a breast oncologist, Dr. Blau has taken leadership roles in developing breast cancer program of excellence in her region. She is also very involved with clinical research program at Northwest Medical Specialties where she is the Medical Director for Hematology-Oncology division and is the head of the Precision Medicine program.

She is one of the founding members and the President/CEO of the Quality Cancer Care Alliance Network that is a national organization to form a value based care organization to improve the cost and quality of cancer patients treated in independent practices throughout the nation. She is also the immediate past President of Washington State Medical Oncology Society (WSMOS), and a member of All4cure as a Clinical Oncologist.

Cathy J. Bradley, PhD
University of Colorado Cancer Center

Cathy J. Bradley, Ph.D., is the Associate Dean for Research in the Colorado School of Public Health and the Deputy Director of the University of Colorado Cancer Center. She holds the Grohne Chair for Cancer Prevention and Control Research. Prior to joining the University of Colorado, she was the founding Chair of the Department of Healthcare Policy and Research, and Associate Director of Cancer Prevention and Control at Virginia Commonwealth University School of Medicine. Dr. Bradley is an internationally recognized expert in health services research and health economics. Her expertise is in labor market outcomes of cancer survivors, health policy, and health disparities. Dr. Bradley is on the editorial board of the *Journal of Cancer Survivorship*, and is a member of the National Academies of Sciences, Engineering, and Medicine National Cancer Policy Forum.

Alicyn Campbell, MPH
AstraZeneca

Alicyn Campbell is currently Head of Digital Health Oncology R&D at AstraZeneca. Alicyn has over 12 years of experience in Health Outcomes Research. Most recently, she served as the Global Head of Patient Centered Outcomes Research at Genentech/Roche. In that capacity, she was responsible for leadership in the assessment of the patient experience and consulted widely with the FDA and international regulators.

She achieved the first ever novel FDA patient reported outcome data approved in label for Hycela and was also responsible for novel patient-reported efficacy data for Hemlibra. She is the Founder, Executive Sponsor and Co-chair of Industry PRO-CTCAE Working Group, recognised as part of the 'Cancer Moonshot' initiative by former US Vice President Biden, and is a frequent research collaborator to Friends of Cancer Research and LUNGevity.

She has also authored several significant scientific publications and presentations, latest in The Lancet Oncology.

Andrea Downing, BA
The Light Collective

Andrea Downing is a Community Data Organizer, security researcher, and advocate hereditary cancer community. In 2018, she discovered the security vulnerability that affected all closed groups on Facebook. Through her work as co-founder of The Light Collective, she is focused on data-sharing for the benefit of patient communities.

Andrea began her work in patient advocacy in 2013, as media spokesperson for one of the plaintiffs in Association of Molecular Pathology vs. Myriad Genetics. She served on the organizing team at Stanford Medicine X.

Dave Dubin
AliveAndKickn

In 1997 at age 29, David Dubin was surprised to learn of his colon cancer diagnosis. Although his grandfather and father both had colon cancer, he didn't associate his bleeding and cramping to symptoms of the disease. Neither did his primary care physician who neglected to recommend a colonoscopy, despite his family history. Not until several months later when he finally saw a specialist did David learn he had colon cancer. It wasn't until 2007 and a second colon cancer diagnosis that David had genetic tested and found out he has Lynch syndrome. David Dubin is now a three-time cancer survivor and patient with Lynch Syndrome, a genetic mutation that predisposes individuals to cancer. David is a fierce advocate and public speaker for awareness, screening and genetic testing. As a founder of AliveAndKickn, a patient-centered nonprofit organization dedicated to education, advocacy, and research of Lynch Syndrome, David is committed to actively helping patients and researchers combat this disease. Along with his wife Robin, David has developed AliveAndKickn to focus on providing resources for Lynch syndrome patients and developing innovative tools like The HEROIC Registry to further research. They continue to work towards expanding outreach and education about Lynch syndrome in the clinical communities and to the general public. AliveAndKickn's mission is to improve the lives of individuals and families affected by Lynch Syndrome and associated cancers through research, education, and screening.

David has also turned his passion for genetic testing into a career, as he is also Vice President of Sales for Kailos Genetics, a CLIA approved NGS lab founded in 2010 and based in Huntsville's HudsonAlpha Institute for Biotechnology.

Deborah Estrin, PhD
Cornell Tech

Deborah Estrin is a Professor of Computer Science at Cornell Tech in New York City where she founded the Jacobs Institute's Health Tech Hub. She holds The Robert V. Tishman Founder's Chair and serves as the Associate Dean for Impact. Her research interests are at the intersection of user-centric health applications, personalization, and privacy. She is currently serving as a part-time Amazon Scholar. Her honors include: The American Academy of Arts and Sciences (2007), The National Academy of Engineering (2009), The IEEE Internet Award (2017), MacArthur Fellow (2018), and The National Academy of Medicine (2019).

Previously, Estrin was on the UCLA faculty where she was the Founding Director of the NSF Center for Embedded Networked Sensing (CENS), pioneering the development of mobile and wireless systems to collect and analyze real time data about the physical world and the people who occupy it.

Kadija Ferryman, PhD
NYU Tandon School of Engineering

Kadija Ferryman is a cultural anthropologist whose research centers on the social, ethical, cultural, and policy dimensions of digital health technology. Specifically, her research examines how genomics, digital medical records, and artificial intelligence impact racial disparities in health. Dr. Ferryman is Industry Assistant Professor at NYU's Tandon School of Engineering, where she directs the ethics and technology curriculum. Before her training as an anthropologist, Ferryman was a policy researcher at the Urban Institute in Washington, DC. She is an affiliate at the Data & Society Research Institute and at the Center for Critical Race and Digital Studies. She also serves on the institutional review board for the National Institutes of Health's All of Us Research Program. Dr. Ferryman received her BA in anthropology from Yale University and her PhD in anthropology from the New School for Social Research.

Thomas J. Fuchs, DrSc
Memorial Sloan Kettering Cancer Center
Weill-Cornell Graduate School of Medical Sciences

Dr. Fuchs is the Director of Computational Pathology at Memorial Sloan Kettering Cancer Center and teaches biomedical machine learning as an Associate Professor at Weill-Cornell in New York City. His passion for the tremendous potential of large-scale machine learning in medicine resulted in him leading the transformation of pathology from a qualitative to a quantitative discipline at Memorial Sloan Kettering—the world's leading cancer center. Previously, Thomas completed his Postdoctoral research with a focus on computer vision, medical imaging at Caltech and received his Ph.D. in Machine Learning from ETH Zurich. He also worked as a rocket scientist at NASA's Jet Propulsion Laboratory, where he developed computer vision systems for space exploration.

Yann Joly, PhD, FCAHS, AdE
McGill University

Yann Joly, Ph.D. (DCL), FCAHS, Ad.E. is the Research Director of the Centre of Genomics and Policy (CGP). He is an Associate Professor at the Faculty of Medicine, Department of Human Genetics cross-appointed at the Bioethics Unit, at McGill University. He was named advocatus emeritus by the Quebec Bar in 2012 and Fellow of the Canadian Academy of Health Sciences in 2017.

Prof. Joly is a member of the Canadian Commission for UNESCO (CCU) Sectoral Commission for Natural, Social and Human Sciences. He is the current Chair of the Bioethics Workgroup of the International Human Epigenome Consortium (IHEC) and Co-Lead the regulatory and ethics work stream of the Global Alliance for Genomics and Health (GA4GH). He was Chair (2017-2019) of the Ethics and Governance Committee of the International Cancer Genome Consortium (ICGC). He is also a member of the Human Genome Organization (HUGO) Committee on Ethics, Law and Society (CELS).

Prof. Joly's research interests lie at the interface of the fields of scientific knowledge, health law (biotechnology and other emerging health technologies) and bioethics. He created the first international genetic discrimination observatory (GDO https://gdo.global/en/gdo-description) in 2018. He has published his findings in over 150 peer-reviewed articles featured in top legal, ethical and scientific journals. He served as a legal advisor on multiple research ethics committees in the public and private sectors. Prof. Joly also sits on editorial committees and acts as a reviewer for a wide range of publications in his field. In 2012, he received the Quebec Bar Award of Merit (Innovation) for his work on the right to privacy in the biomedical field.

Nancy Kass, ScD
Johns Hopkins University

Nancy Kass, ScD, is Vice Provost for Graduate and Professional Education, Johns Hopkins University and Phoebe R. Berman Professor of Bioethics and Public Health in the JHU Berman Institute of Bioethics and Bloomberg School of Public Health, and Professor of Health Policy and Management. In 2009-2010, Dr. Kass was based in Geneva, Switzerland, working with the World Health Organization (WHO). Dr. Kass received her B.A. from Stanford University, completed doctoral training in health policy from the Johns Hopkins School of Public Health and post-doctoral training at the Kennedy Institute of Ethics, Georgetown University. As Vice-Provost, Dr. Kass focuses on the quality of PhD education and postdoctoral training, including promoting transparency about programs, diversity of the student body, professional development, and mentoring. In her faculty role, Dr. Kass conducts empirical work in bioethics, public health, and human research with publications on global and U.S. research ethics, public health ethics, and the learning healthcare system. Dr. Kass chairs the NIH All of Us Research Program Central IRB; she previously served as consultant to the President's Advisory Committee on Human Radiation Experiments, the National Bioethics Advisory Commission, and the National Academy of Sciences. Dr. Kass is an elected member of the National Academy of Medicine (formerly Institute of Medicine) and an elected Fellow of the Hastings Center.

Lisa Kennedy Sheldon, PhD, ANP-BC, AOCNP®, FAAN
Oncology Nursing Society

Lisa Kennedy Sheldon is the Clinical and Scientific Affairs Liaison at the Oncology Nursing Society (ONS). She connects the ONS members and the oncology nursing profession with professional organizations, advocates and policy makers to support oncology nurses, advanced practice nurses and researchers, and develop leaders to transform cancer care.

As experienced faculty and former Associate Professor at the University of Massachusetts-Boston, Dr. Sheldon has taught nurses for over 25 years at the undergraduate and masters levels as well as PhD students in health policy with a focus on disparities in cancer care and outcomes. Dr. Sheldon's program of research, supported by the American Cancer Society and the Oncology Nursing Foundation, has focused on patient-provider communication and psychosocial issues in cancer care. Dr. Sheldon has received numerous honors and awards including induction as a fellow in the American Academy of Nursing (FAAN).

Dr. Sheldon is passionate about improving cancer care and nursing education nationally and globally. Her work has included programs on oncology care, patient-provider communication, symptom management and palliative care, safe handling of antineoplastic drugs, and health promotion and cancer prevention. She serves on the National Cancer Policy Forum, and was co-chair of the Global Nursing Caucus and past president of the Theta Alpha chapter of Sigma Theta Tau International. She has volunteered in numerous countries with ONS, American Society of Clinical Oncology, Oman Cancer Association, Middle East Cancer Consortium and Health Volunteers Overseas. Dr. Sheldon served as the Editor of the Clinical Journal of Nursing and authored numerous publications and three books including Communication for Nurses: Talking with Patients. Dr. Sheldon continues to practice as a certified oncology nurse practitioner (AOCNP®) at St. Joseph Hospital in Nashua, NH.

Paul Kluetz, MD
U.S. Food and Drug Administration

Paul Kluetz is a medical oncologist and Deputy Director of the Oncology Center of Excellence (OCE) at the U.S. FDA. His interests include trial design and endpoint selection to expedite drug development and define clinical benefit in oncology trials. His work has included the initiation and direction of the OCE's patient-focused drug development program which has been instrumental in FDA's efforts to review, analyze and communicate patient reported outcomes (PRO), wearable technologies, and other data sources assessing symptoms and function in both the clinical trial and "real-world" settings. Dr. Kluetz has also played an important role in the Project Renewal effort to update longstanding oncology drug labels, and is active in efforts to advance patient-friendly, efficient study designs including pragmatic and decentralized trials and expansion of eligibility criteria. Dr. Kluetz remains clinically active, caring for patients and supervising medical residents at the Georgetown University Hospital.

Allison W. Kurian, MD, MSc
Stanford University School of Medicine

Dr. Kurian's research focuses on the identification of women with elevated breast and gynecologic cancer risk, and on the development and evaluation of novel techniques for early cancer detection and risk reduction. As Director of the Stanford Women's Clinical Cancer Genetics Program, her practice centers on women at high risk of breast and gynecologic cancers.

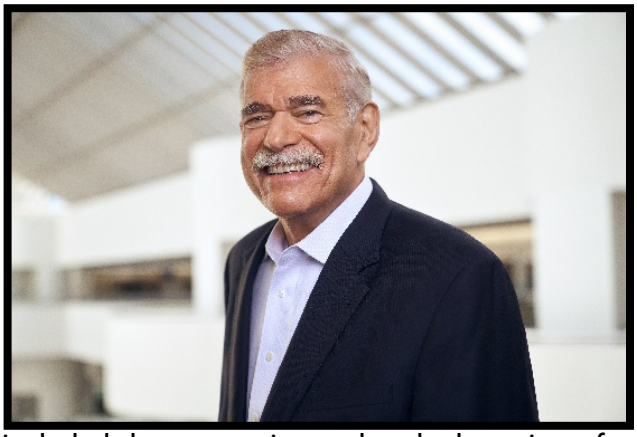
Dr. Kurian earned her M.D. degree at Harvard Medical School, completed residency in Internal Medicine at Massachusetts General Hospital, then trained in Medical Oncology and earned her M.Sc. degree in Epidemiology at Stanford University. She has published 180 peer-reviewed articles, many in high-impact journals such as JAMA, the Journal of Clinical Oncology and the Journal of the National Cancer Institute. Dr. Kurian's research has been supported by grants from the National Institutes of Health, California Breast Cancer Research Program, Komen for the Cure Foundation, Breast Cancer Research Foundation, BRCA Foundation and others. Dr. Kurian serves on several national committees

that advance the clinical and research mission of women's cancer genetics: she develops evidence-based practice guidelines as a member of the National Comprehensive Cancer Network and has led the American Society of Clinical Oncology's Scientific Program Committee for Cancer Epidemiology and Prevention.

Mia Levy, MD, PhD
Rush University

Dr. Mia A. Levy is the Sheba Foundation Director of the Cancer Center at Rush University Medical Center and the System Vice President for Cancer Services at Rush System for Health. She is an Associate Professor of Medicine in the Division of Hematology and Oncology and a practicing medical oncologist specializing in the treatment of breast cancer and precision oncology.

Dr. Levy's research mission is to develop and disseminate learning cancer systems that deliver data and knowledge driven clinical decision support across the continuum of cancer care and research. To accomplish this, she applies biomedical informatics and implementation science methods to real-world problems in healthcare delivery systems. As the director of the Cancer Center at Rush University Medical Center, Dr. Levy is leading efforts to create a learning healthcare system as part of the strategic direction for continuous discovery and improvement of cancer outcomes embedded into routine clinical practice. Precision cancer medicine implementation continues to be a driving use case for the learning systems framework, combining integration of genomic data into clinical workflows within the electronic health record, knowledge driven clinical decision support systems driven by the My Cancer Genome knowledge base, and infrastructures for secondary use of data for discovery both locally and as part of international data consortium.



J. Leonard Lichtenfeld, MD, MACP
American Cancer Society

J. Leonard (Len) Lichtenfeld, MD, MACP, serves as Deputy Chief Medical Officer for the American Cancer Society at its Global Headquarters in Atlanta.

Dr. Lichtenfeld joined the Society in 2001 as a medical editor, and in 2002 assumed responsibility for managing the newly-created Cancer Control Science Department, which included the prevention and early detection of cancer, emerging cancer science and trends, health equity, quality of life for cancer patients, the science of cancer communications, and the role of nutrition and physical activity in cancer prevention and cancer care.

In 2014, Dr. Lichtenfeld joined the Office of the Chief Medical Officer as Deputy Chief Medical Officer, where he provided extensive support to a number of Society colleagues and activities. He served as interim Chief Medical Officer from November, 2018 until October 2019.

As a result of his over four decades of experience in cancer care, Dr. Lichtenfeld is frequently quoted in the print and electronic media regarding the Society's positions on a number of important issues related to cancer.

He has testified frequently in legislative and regulatory hearings, and participated on numerous panels regarding cancer care, research, advocacy and related topics. He has served on a number of advisory committees and boards for organizations that collaborate with the Society to reduce the burden of cancer nationally and worldwide.

He is well known for his blog (Dr. Len's Cancer Blog) which first appeared in 2005 and which continues to address various topics related to cancer research and treatment.

A board certified medical oncologist and internist who was a practicing physician for over 19 years, Dr. Lichtenfeld has long been engaged in health care policy on a local, state, and national level. He is active in several state and national medical organizations and has a long-standing interest in professional legislative and regulatory issues related to health care including physician payment, medical care delivery systems, and health information technology.

Dr. Lichtenfeld is a graduate of the University of Pennsylvania and Hahnemann Medical College (now Drexel University College of Medicine) in Philadelphia. His postgraduate training was at Temple University Hospital in Philadelphia, Johns Hopkins University School of Medicine, and the National Cancer Institute in Baltimore. He is a member of Alpha Omega Alpha, the national honor medical society. Dr. Lichtenfeld has received several awards in recognition of his efforts on behalf of his colleagues and his professional activities. He has been designated a Master of the American College of Physicians in acknowledgement of his contributions to internal medicine. Dr. Lichtenfeld is married, and resides in Atlanta, Georgia.

Bradley Malin, PhD
Vanderbilt University Medical Center

Bradley Malin, Ph.D., is the Vice Chair for Research in the Department of Biomedical Informatics at Vanderbilt University Medical Center. He is also a Professor of Biomedicla Informatics, Biostatistics, and a Professor of Computer Science at Vanderbilt University. He co-directs the Vanderbilt Health Data Science (HEADS) Center and an NIH Center of Excellence in Ethical, Legal, and Social Implications Research on genomics and privacy.

His research is funded through various grants from the National Science Foundation (NSF), National Institutes of Health (NIH), and Patient Centered Outcomes Research Institute (PCORI) to construct technologies that enable privacy and analytics in the context of real world organizational, political, and health information architectures. He currently serves the co-chair of the Committee on Access, Privacy, and Security of the All of Us Research Program of the U.S. Precision Medicine Initiative and is an appointed member of the Technical Anonymisation Group of the European Medicines Agency. He is an elected fellow of the National Academy of Medicine, American College of Medical Informatics and was honored as a recipient of the Presidential Early Career Award for Scientists and Engineers (PECASE).

Deven McGraw, JD, MPH, LLM
Ciitizen

Deven McGraw is the Chief Regulatory Officer for Ciitizen, a consumer health technology start-up. Prior to joining Ciitizen, she directed U.S. health privacy and security through her roles as Deputy Director, Health Information Privacy at the HHS Office for Civil Rights (the office that oversees HIPAA policy development and enforcement) and Chief Privacy Officer (Acting) of the Office of the National Coordinator for Health IT. Widely recognized for her expertise in health privacy and security, she directed the Health Privacy Project at the Center for Democracy & Technology (a nonprofit civil liberties organization) for six years and led the privacy and security policy work for the HITECH Health IT Policy Committee. She also served as the Chief Operating Officer of the

National Partnership for Women and Families. She has also advised health industry clients on HIPAA compliance and data governance while a partner at Manatt, Phelps & Phillips, LLP. Deven graduated magna cum laude from Georgetown University Law Center and has a Masters of Public Health from Johns Hopkins University.

Neal J. Meropol, MD
Flatiron Health

Neal J. Meropol, MD is a medical oncologist, clinical investigator and outcomes researcher who serves as Vice President and Head of Medical and Scientific Affairs at Flatiron Health. In this role, he leads efforts and engages partners to leverage Flatiron's technology platforms and provider network to gain insights from real world data that accelerate research and improve quality of care for cancer patients. Prior to joining Flatiron, he served as Professor and Chief of the Division of Hematology and Oncology at University Hospitals Cleveland Medical Center and Case Western Reserve University, and Associate Director for Clinical Research at the Case Comprehensive Cancer Center.

Dr. Meropol's research contributions span drug development and health services research, including evaluation of new agents, predictors of response and outcome, development of tools to overcome barriers to clinical trial participation, and assessment of the economic impact of care. He is an appointed member to the NCI Director's Clinical Trials and Translational Research Advisory Committee (CTAC), and served two terms as Chair of the National Cancer Institute Gastrointestinal Cancer Steering Committee. Dr. Meropol completed a four-year term as an elected member of the American Society of Clinical Oncology (ASCO) Board of Directors. A committed educator, Dr. Meropol served as faculty and chair of the AACR/ASCO Methods in Clinical Research Vail Workshop, and ASCO Leadership Development Program. He has authored more than 300 manuscripts, book chapters, and editorials related to cancer prevention, treatment, decision making, and health economics.

Dr. Meropol received his undergraduate degree from Princeton University in Philosophy, and MD from Vanderbilt University. He was a resident in Internal Medicine at Case Western Reserve University, and completed hematology and medical oncology fellowships at the University of Pennsylvania. He spent a sabbatical at the Leonard Davis Institute of Health Economics at the Wharton School of the University of Pennsylvania.

Randall A. Oyer, MD
Penn Medicine Lancaster General Health

Randall A. Oyer, MD, is a practicing medical oncologist at the Ann B. Barshinger Cancer Institute at Penn Medicine Lancaster General in Lancaster, Pennsylvania. Dr. Oyer serves as the Medical Director of the Cancer Institute, Medical Director of Oncology, Chairman of Cancer Committee, Chair of the Oncology Physicians Advisory Council, and Medical Director of the Cancer Risk Evaluation (Cancer Genetics) Program at Penn Medicine Lancaster General.

Dr. Oyer is a member of the Cancer Service Line Executive Committee and the Cancer Service Line Quality Committee at the Abramson Cancer Center- University of Pennsylvania, Philadelphia.

Dr. Oyer is currently serving as President of the Association of Community Cancer Centers, Rockville, Maryland. Dr. Oyer is an ex-officio Commissioner of the American College of Surgeons Commission on Cancer, representing the Association of Community Cancer Centers.

Ravi Parikh, MD, MPP
University of Pennsylvania

Ravi B. Parikh, MD, MPP, is an Assistant Professor of Medical Ethics and Health Policy at the University of Pennsylvania and a Staff Physician at the Corporal Michael J. Crescenz VA Medical Center. Dr. Parikh is a practicing oncologist with expertise in delivery system reform and informatics. His work has focused on two core areas: (1) the use of predictive analytics to improve routine patient care, particularly for those with advanced illnesses such as cancer, and (2) quality of life and survivorship care among individuals with cancer. He specializes in observational data analysis and pragmatic clinical trials.

Dr. Parikh's work on medical technology and advanced illness in leading academic journals including Science, The New England Journal of Medicine, The Journal of the American Medical Association, and the Journal of Clinical Oncology. He writes frequently for The Washington Post and other popular press venues, and he is a columnist at Medscape. He serves as Senior Clinical Advisor at the Coalition to Transform Advanced Care (C-TAC), was elected to the National Council of Resident/Fellow Members of the American College of Physicians, and has advised for-profit and non-profit organizations including AARP Services, Inc. and the Healthy

Living Center of Excellence. Ravi worked on accountable care organization implementation as a Rappaport Fellow in the Massachusetts State House in 2010; his legislative recommendations earned a commendation from the Massachusetts Speaker of the House and were incorporated into landmark payment reform legislation passed in 2012.

Dr. Parikh is a graduate of Harvard Medical School, Harvard College, and the John F. Kennedy School of Government. He completed a residency in internal medicine at Brigham and Women's Hospital and a fellowship in Hematology and Oncology at the University of Pennsylvania. He has received the Conquer Cancer Foundation Young Investigator Award, AMA Foundation Excellence in Medicine Leadership Award, and the American Geriatrics Society Edward Henderson Award, and was named a MedTech Boston 40 Under 40 Healthcare Innovator.

Susan K. Peterson, PhD, MPH
The University of Texas MD Anderson Cancer Center

Susan K. Peterson, PhD, MPH, is Professor of Behavioral Science at MD Anderson Cancer Center. Her research focuses on psychosocial and behavioral outcomes of genetic testing for hereditary cancer syndromes in cancer survivors and their families, as well as the integration of genetic services into general oncology care. Her work centers on cancer survivors' and families' decision-making about genetic testing and receiving genetic test results, and the subsequent psychological and behavioral impact of those decisions, including the impact on the quality of life and related factors. A cross-cutting theme of Dr. Peterson's research is the development and evaluation of novel, e-Health interventions for populations at risk for hereditary cancer and cancer survivors, including internet- and game-based behavior change interventions for adolescents and young adults. Dr. Peterson also leads research to develop and evaluate novel sensor-based and mobile technology applications for behavioral assessment and intervention.

Andrea L. Pusic, MD, MHS, FACS, FRCSC
Brigham and Women's Hospital

Andrea Pusic, MD, MHS, FACS, FRCSC, is Chief of Plastic and Reconstructive Surgery at Brigham and Women's Hospital. Dr. Pusic studied medicine at the Cumming School of Medicine (University of Calgary) and later earned her Master of Public Health at Johns Hopkins University. She completed a general surgery residency at Dalhousie University in Nova Scotia and a plastic surgery residency at McGill University in Montreal, followed by a plastic and reconstructive surgery fellowship at Memorial Sloan-Kettering Cancer Center (MSKCC).

Dr. Pusic is a leader in the area of patient-reported outcomes and surgical experience. At Brigham Health, she leads the Patient-Reported Outcomes, Value & Experience (PROVE) Center. The mission of the PROVE center is to expand the collection, analysis and use of patient-reported outcome data in Surgery. She is co-principal investigator of a study funded by the Patient-Centered Outcomes Research Institute (PCORI) that examines how electronic patient-reporting of symptoms may improve surgical care. The patient-reported outcomes measure she developed for breast surgery, the BREAST-Q, has been widely adopted for research and clinical care and serves as the basis for development of other outcome measures in surgery.

Kristen B. Rosati, JD
Coppersmith Brockelman, PLC

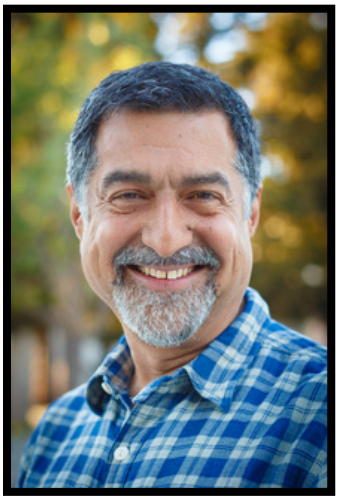
Kristen Rosati is a partner at Coppersmith Brockelman, PLC, and is considered one of the nation's leading "Big Data" and HIPAA compliance attorneys. She also has deep experience in data sharing for research and clinical integration initiatives, clinical research compliance, biobanking and genomic privacy, and health information exchange. Kristen is a Past President of the American Health Lawyers Association (AHLA), the nation's largest educational organization devoted to legal issues in the healthcare field with almost 15,000 members.

Kristen has been listed in Best Lawyers in America for health care since 2007 and was Best Lawyers' 2017 and 2014 Phoenix Health Care Law "Lawyer of the Year." She was chosen as one of Outstanding Business Women in Arizona in 2017 and one of the 50 Most Influential

Women in Arizona Business in 2013. She received the Health Care Leadership Award for Legal Advocate of the Year in 2014, and was recognized in Arizona Business Leaders 2015-2018 and Arizona's Top 100 Lawyers in 2014- 2018 by Arizona Business Magazine. She is also recognized in Super Lawyers and Chambers for health care. Kristen received her B.A., with high honors, and her J.D., cum laude, from the University of Michigan. She clerked for the late Judge Thomas Tang of the U.S. Court of Appeals for the Ninth Circuit and for Judge Earl H. Carroll of the U.S. District Court for the District of Arizona.

Fred B. Schneider, PhD
Cornell University

Fred B. Schneider (NAE), Chair of the Forum on Cyber Resilience, is the Samuel B. Eckert Professor of Computer Science at Cornell University. He joined Cornell's faculty in Fall 1978, having completed a Ph.D. at Stony Brook University and a B.S. in engineering at Cornell in 1975. Dr. Schneider's research has always concerned various aspects of trustworthy systems —systems that will perform as expected, despite failures and attacks. Most recently, his interests have focused on system security. His work characterizing what policies can be enforced with various classes of defenses is widely cited, and it is seen as advancing the nascent science base for security. He is also engaged in research concerning legal and economic measures for improving system trustworthiness. Dr. Schneider was elected a fellow of the American Association for the Advancement of Science (AAAS;1992), the Association of Computing Machinery (1995), and the Institute of Electrical and Electronics Engineers (IEEE; 2008). He was named a professor-at-large at the University of Tromso (Norway) in 1996 and was awarded a doctor of science (honoris causa) by the University of Newcastle-upon-Tyne in 2003 for his work in computer dependability and security. He received the 2012 IEEE Emanuel R. Piore Award for contributions to trustworthy computing through novel approaches to security, fault-tolerance and formal methods for concurrent and distributed systems. The U.S. National Academy of Engineering (NAE) elected Dr. Schneider to membership in 2011, and the Norges Tekniske Vitenskapsakademi (Norwegian Academy of Technological Sciences) named him a foreign member in 2010. He is currently a member of the National Academies of Sciences, Engineering, and Medicine's Computer Science and Telecommunications Board and is founding chair of the Academies' Forum on Cyber Resilience.



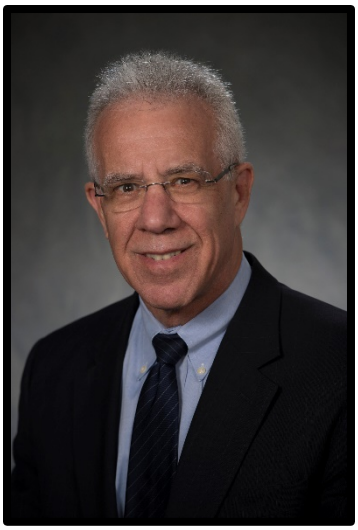
Anil Sethi, MS
Ciitizen

Anil Sethi is the CEO of Ciitizen, a Silicon Valley startup helping patients collect, organize, and securely share all their digital health data—converting all text narratives and notes into computable and standardized data. Apple acquired Sethi's consumer Health Records company Gliimpse in 2016, where he helped rerelease Apple Health Records. Anil served as a Director of Apple Health until leaving in 2017 to take care of his little sister Tania, who died from Stage IV Metastatic Breast Cancer. Amongst his 7 healthcare ventures, he's seen abject failure, three successful exits (WebMD, Citrix, Apple) and a Nasdaq IPO.

Anand Shah, MD, MPH
U.S. Food and Drug Administration

Anand Shah, M.D. is the Deputy Commissioner for Medical and Scientific Affairs. Dr. Shah leads the agency's operations as it relates to medical and scientific affairs. He is responsible for developing and leading high-priority FDA policy initiatives and oversees cross-agency teams in support of FDA's public health mission. He recently served in two senior leadership roles at the Centers for Medicare & Medicaid Services (CMS). Dr. Shah was the Senior Medical Advisor for Innovation at CMS, where he was the primary counselor to the Administrator for agency-wide policy related to medical and scientific innovation. Previously at CMS, he served as Chief Medical Officer of the Center for Medicare & Medicaid Innovation (CMMI) where he led the clinical design of novel payment and service delivery models. Dr. Shah started his federal career at the FDA where he provided guidance to industry and academia on medical product development, clinical trial design, and regulatory pathways to accelerate public access to new therapies. Prior to his government service, Dr. Shah served as an advisor to a U.S. venture capital firm.

Dr. Shah concurrently earned his M.D. from the University of Pennsylvania and an M.P.H. in health care management and policy from the Harvard School of Public Health. Dr. Shah graduated with honors from Duke University with a degree in economics. He also served as a Canada-U.S. Fulbright Scholar.



Lawrence N. Shulman, MD, MACP, FASCO
University of Pennsylvania

Lawrence N. Shulman, MD, is Professor of Medicine at the Perelman School of Medicine, University of Pennsylvania, the Deputy Director for Clinical Services of the Abramson Cancer Center at the University of Pennsylvania, and Director of the Center for Global Cancer Medicine. In this capacity, he leads the Cancer Quality program and strategic development of Cancer Services across the 6 Penn hospitals and their associated ambulatory cancer centers. He received his MD from Harvard Medical School, and trained in Hematology and Oncology at the Beth Israel Hospital in Boston, MA.

Dr. Shulman is currently Chair of the Commission on Cancer and serves on the National Cancer Policy Forum of the National Academy. He is the former Chair of the American Society of Clinical Oncology Quality of Care Committee and the Commission on Cancer's Quality Integration Committee. He is a member of the NCCN Best Practices Committee.

A specialist in the treatment of patients with breast cancer, his research includes development of new cancer therapies, and implementation of cancer treatment programs in low-resource settings.

In this regard, Dr. Shulman serves as Senior Oncology Advisor to the non-profit organization Partners In Health (PIH). The PIH mission includes the establishment of national cancer treatment programs with the Ministries of Health in Rwanda and Haiti, programs for which he plays a seminal leadership role. He sits on the Vice Chancellor's Advisory Council for Rwanda's University for Global Health Equity. In addition, he helps to lead the development of the national oncology program in Botswana through the Botswana-UPenn Partnership. Dr. Shulman is a former member of ASCO's International Affairs Committee and their Task Force on Global Oncology as an Academic Career. He led the World Health Organization's review and revision of their Essential Medicines for Cancer from 2014-2017.

Lara Strawbridge, MPH
Centers for Medicare & Medicaid Services

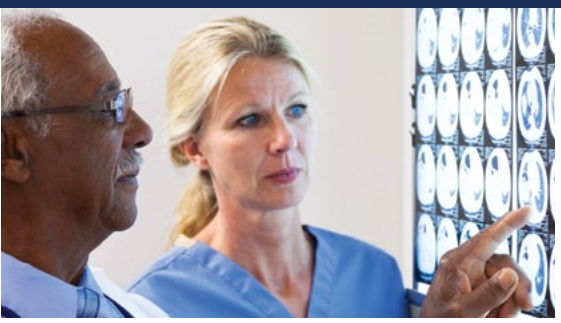
Lara Strawbridge is the Director of the Division of Ambulatory Payment Models in the Patient Care Models Group in the Center for Medicare and Medicaid Innovation (CMMI). In this role, Ms. Strawbridge leads CMS's efforts on physician specialty models, such as the Oncology Care Model and the proposed Radiation Oncology Model, and Part B drug issues. Prior to taking on the Division Director role, Ms. Strawbridge led the Oncology Care Model and also previously worked in CMMI's Research and RapidCycle Evaluation Group. Ms. Strawbridge began her career in health policy and research at the Institute of Medicine and previously was a teacher in Hertfordshire, England, and Washington, DC. Ms. Strawbridge earned her MPH from Johns Hopkins Bloomberg School of Public Health.

Samuel Takvorian, MD, MS
University of Pennsylvania

Samuel Takvorian, MD, MS is an Instructor in the Division of Hematology and Oncology at the University of Pennsylvania Perelman School of Medicine. He graduated from Harvard Medical School and completed his Internal Medicine residency at Brigham and Women's Hospital in Boston, MA. He served as Chief Fellow while training in Hematology and Oncology at University of Pennsylvania, where he also earned a Master of Science in Health Policy Research. His interest in health care policy dates back to an AmeriCorps year, leading health advocacy efforts in a community health center during the implementation of Massachusetts health reform. Later work at Harvard Business School and the Alliance for Health Reform in Washington, DC inspired him towards a career in health services research. He remains committed to researching questions pertaining to the value of cancer care, encompassing rigorous measurement of both traditional and patient reported outcomes, as well as the costs of care; and to improving the implementation of research findings and innovations into routine practice. He has received multiple mentorship awards for his commitment to medical education, and was awarded the Jane Alavi Award for clinical excellence during fellowship. He maintains a robust clinical practice in genitourinary oncology.

NATIONAL CANCER POLICY FORUM

ABOUT THE FORUM



The National Cancer Policy Forum serves as a trusted venue in which experts can identify emerging high-priority policy issues in cancer research and 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 stakeholders about critical policy issues through published reports and often inform consensus committee studies. 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

#NatlCancerForum

To receive updates on the National Cancer Policy Forum, visit **nationalacademies.org/NCPF**

The National Academies of SCIENCES ENGINEERING MEDICINE

Upcoming Workshops

Opportunities and Challenges for Using Digital Health Applications in Oncology

July 13-14, 2020

The National Cancer Policy Forum, in collaboration with the Forum on Cyber Resilience, is convening a workshop to examine the role of digital health applications in oncology research and care. Workshop speakers will discuss topics such as:

- Exemplars of novel digital health applications, including an emphasis on patient-facing technologies
- Regulatory priorities
- Ethical, security, governance, and payment considerations
- Opportunities to improve data availability and use in EHRs and large databases
- Participant reactions and recommendations for the path forward

Workshop website: https://www.nationalacademies.org/event/07-13-2020/opportunities-and-challenges-for-using-digital-health-applications-in-oncology-a-workshop

WORKSHOP SERIES ON OLDER ADULT POPULATIONS

Collaborative series convened by:
National Cancer Policy Forum
Forum on Drug Discovery, Development, and Translation
Forum on Aging, Disability, and Independence

Drug Research and Development for Adults Across the Older Age Span

August 5-6, 2020

There is a lack of evidence about the appropriate use of drugs in older adult populations, which hampers decision making about how to optimize care for older adults. A major contributor to this evidence gap is that older adults are vastly underrepresented in clinical trials. This workshop will convene stakeholders to discuss the challenges and opportunities in drug research and development for older adult populations, including the barriers that impede safety and efficacy studies in these populations. Workshop presentations and discussions will highlight opportunities to better engage older adults in clinical research and strategies to generate evidence-based prescribing information for older adult populations.

Workshop website: https://www.nationalacademies.org/event/08-05-2020/drug-research-and-development-for-older-adult-populations-a-workshop

Improving the Evidence Base for Treatment Decision Making for Older Adults with Cancer

Date TBD

Older adults represent the majority of patients diagnosed with cancer and the majority of cancer-related deaths. However, the evidence base to guide treatment decision making among older adults with cancer is sparse, primarily because older adults are underrepresented in clinical trials, and trials designed specifically for older adults are rare. This workshop will examine challenges and opportunities to improve the evidence base for treating older adults with cancer, including clinical trial design and analysis strategies, incorporation of geriatric assessments and patient reported outcomes in clinical trials, and the potential for real world data collection from clinical practice to fill evidence gaps.

Workshop website forthcoming

Addressing the Adverse Consequences of Cancer Treatment

November 9-10, 2020

Cancer care is associated with significant physical, mental, and socioeconomic consequences. This workshop will examine the array of short- and long-term toxicities and adverse effects that patients may experience as a result of cancer treatment and consider opportunities to improve quality of life for cancer survivors and their families. Workshop presentations and discussions will focus on topics such as:

- Strategies to better accrue data on short- and long-term effects of cancer and cancer treatment
- Opportunities to redesign cancer treatment to reduce short- and long-term toxicities without compromising treatment effectiveness
- Patient engagement in treatment decision-making and tools to facilitate understanding of risk/benefit tradeoffs
- System-level interventions and best practices for prevention, surveillance, and mitigation of the adverse effects of cancer treatment
- Opportunities to overcome the challenges that prevent uptake and dissemination of evidence-based approaches to address the adverse effects of cancer treatment.

Workshop website: https://www.nationalacademies.org/event/11-09-2020/addressing-the-adverse-consequences-of-cancer-treatment-a-workshop

Recent Workshops and Publications

Advancing Progress in the Development and Implementation of Effective, High-Quality Cancer Screening

Evidence-based screening approaches have contributed to improved patient outcomes, and research continues to develop and evaluate potential new strategies for early cancer detection. However, there are a number of challenges related to ensuring effective, high-quality screening. This workshop examined current issues in cancer screening, including principles and methods of cancer screening; key gaps in the evidence base for cancer screening, as well as statistical and methodologic challenges; validation and implementation of novel screening technologies; patient access to high-quality cancer screening and follow-up care; and shared decision making and communication in cancer screening.

Workshop videos and presentation files: https://www.nationalacademies.org/event/03-02-2020/advancing-progress-in-the-development-and-implementation-of-effective-high-quality-cancer-screening-a-workshop

Applying Big Data to Address the Social Determinants of Health in Oncology

This workshop, held in collaboration with the Committee on Applied and Theoretical Statistics, examined social determinants of health (SDOH) in the context of cancer and considered opportunities to effectively leverage big data to improve health equity and reduce disparities. Presentations and discussions highlighted the influence of SDOH on cancer risk and outcomes; novel data sources and methodologies; data policy and ethical considerations regarding the use of big data in SDOH research; opportunities for collaboration and data sharing; as well as avenues for future research.

Workshop videos and presentation files: https://www.nationalacademies.org/event/10-21-2019/applying-big-data-to-address-the-social-determinants-of-health-in-oncology-a-workshop

Health Literacy and Communication Strategies in Oncology

This workshop, held in collaboration with the Roundtable on Health Literacy, examined opportunities, methods, and strategies to improve the communication of cancer information in a clinic visit, across a health care organization, and among the broader community. Workshop presentations and discussion addressed procedures, policies, and programs to support health literacy needs of patients and families; best practices to improve communication about cancer prevention, detection, treatment, and survivorship; and communication strategies to build public trust and counter inaccurate information about cancer.

Workshop videos and presentation files: https://www.nationalacademies.org/event/07-15-2019/health-literacy-and-communication-strategies-in-oncology-a-workshop

Proceedings: http://www.nationalacademies.org/hmd/Reports/2020/health-literacy-and-communication-strategies-in-oncology-pw.aspx

Workshop Overview: https://www.nap.edu/resource/25664/interactive/

Workshop highlight videos are available at: www.youtube.com/watch?v=M1NjXeG_cgs and www.youtube.com/watch?v=9iyPsTZ7RNw

Developing and Sustaining an Effective and Resilient Oncology Careforce

Advances in cancer research, screening and diagnostic practices, and cancer treatment have led to improved outcomes for patients with cancer and a growing population of cancer survivors, but they have also increased the complexity of cancer care. Demographic trends, new payment models, growing emphasis on interprofessional practice, the widespread adoption of technologies in clinical practice, and a shift to the outpatient care delivery all have a profound effect on the cancer careforce. This workshop examined opportunities to better support the oncology careforce and improve the delivery of high-quality cancer care.

Workshop videos and presentation files: http://nationalacademies.org/hmd/Activities/Disease/NCPF/2019-FEB-11.aspx

Proceedings: https://www.nap.edu/catalog/25533/developing-and-sustaining-an-effective-and-resilient-oncology-careforce-proceedings

Workshop Overview: https://www.nap.edu/resource/25533/interactive/

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- Centers for Disease Control and Prevention
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- American Association for Cancer Research
- American Cancer Society
- American College of Radiology
- American Society of Clinical Oncology
- Association of American Cancer Institutes
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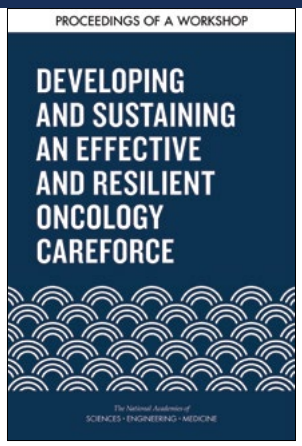
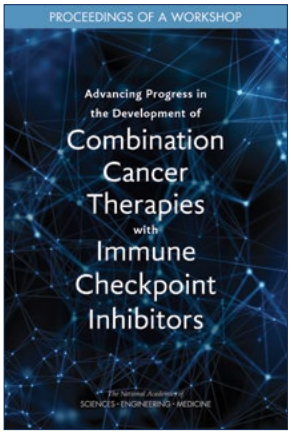
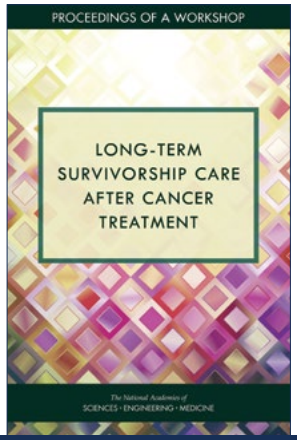
WORKSHOP PROCEEDINGS AND RELATED PUBLICATIONS







WORKSHOP PROCEEDINGS

2020

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

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

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

Enhancing Scientific Reproducibility 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

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

To receive updates on the National Cancer Policy Forum, visit:

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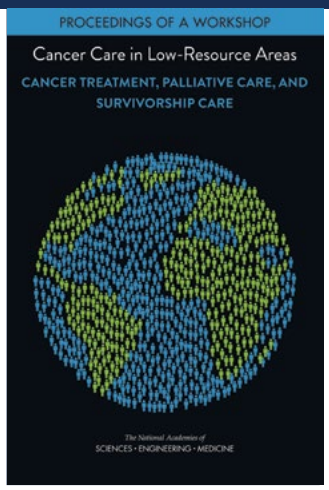
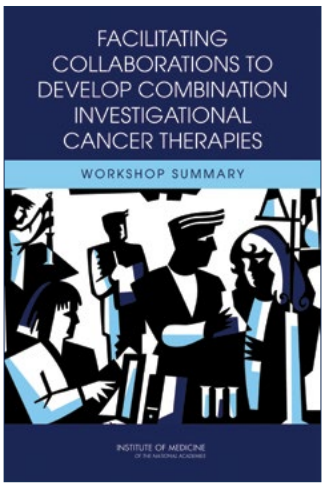
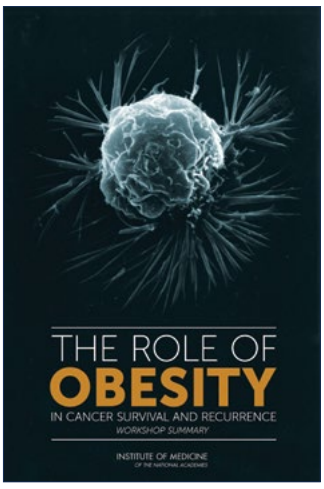






WORKSHOP PROCEEDINGS

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: Workshop Summary *(2013 and 2011)*

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

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: Workshop Proceedings

Nanotechnology and Oncology: Workshop Summary

2010

Direct to Consumer Genetic Testing (with the National Research Council): Summary of a Workshop

Extending the Spectrum of Precompetitive Collaboration in Oncology Research: Workshop Summary

A Foundation for Evidence-Driven Practice: A Rapid Learning System for Cancer Care: Workshop Summary

Policy Issues in the Development of Personalized Medicine in Oncology: Workshop Summary

2009

Assessing and Improving Value in Cancer Care: Workshop Summary

Ensuring Quality Cancer Care Through the Oncology Workforce: Sustaining Care in the 21st Century: Workshop Summary

Multi-Center Phase III Clinical Trials and the NCI Cooperative Group Program: Workshop Summary

2008

Implementing Colorectal Cancer Screening: Workshop Summary

Improving the Quality of Cancer Clinical Trials: Workshop Summary

2007

Cancer-Related Genetic Testing and Counseling: Workshop Proceedings

Cancer in Elderly People: Workshop Proceedings

Implementing Cancer Survivorship Care Planning: Workshop Summary

2006

Effect of the HIPAA Privacy Rule on Health Research: Proceedings of a Workshop

Developing Biomarker-Based Tools for Cancer Screening, Diagnosis, and Treatment: Workshop Summary

RELATED WORK

CONSENSUS STUDY REPORTS BUILDING ON NCPF WORK

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

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

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

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

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

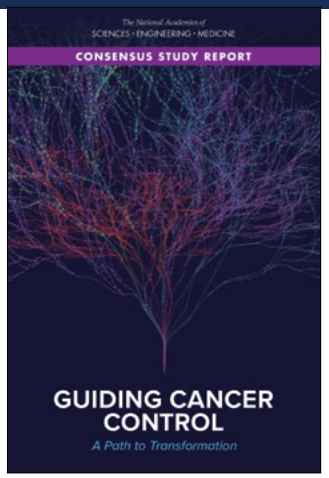
Evolution of Translational Omics: Lessons Learned and the Path Forward (2012)
Report: nap.edu/catalog/13297

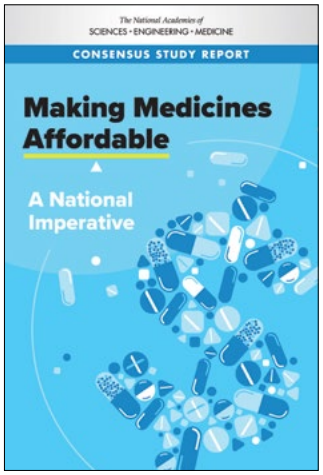
A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program (2010)
Report: nap.edu/catalog/12879

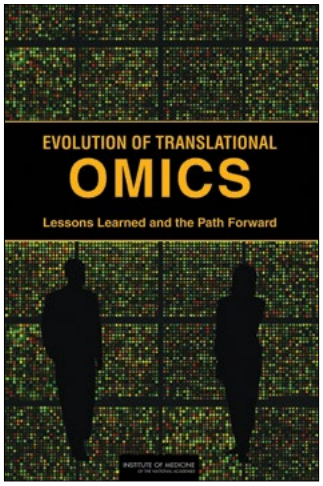
Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease (2010)
Report: nap.edu/catalog/12869

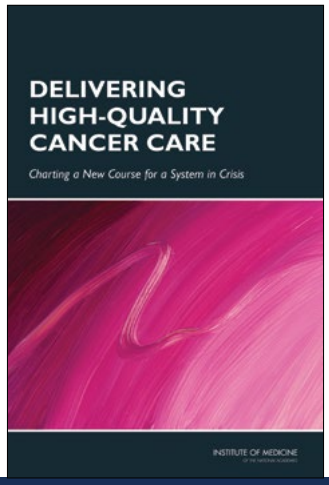
Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research (2009)
Report: nap.edu/catalog/12458

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









INDIVIDUALLY AUTHORED PUBLICATIONS BUILDING ON NCPF WORK

Independent, individually authored articles* in the literature arising from NCPF workshops—and consensus studies building on the work of NCPF—include:

2020

- Shulman, L.N., L.K. Sheldon, and E.J. Benz. 2020. The Future of Cancer Care in the United States—Overcoming Workforce Capacity Limitations. JAMA Oncology. doi:10.1001/jamaoncol.2019.5358 https://jamanetwork.com/journals/jamaoncology/article-abstract/2758839
- Panagiotou, O. A., L. Hoffman-Högg, H. Hricak, S.N. Khleif, M.A. Levy, D. Magnus, M.J. Murphy, B. Patel, R.A. Winn, S.J. Nass, C. Gatsonis, and C.R. Cogle. 2020. Clinical Application of Computational Methods in Precision Oncology: A Review. JAMA Oncol. https://jamanetwork.com/journals/jamaoncology/article-abstract/2765757
- Takvorian, S.U., E. Balogh, S. Nass, V.L. Valentin, L. Hoffman-Hogg, R.A. Oyer, R.W. Carlson, N.J. Meropol, L.K. Sheldon, and L.N. Shulman. 2019. Developing and Sustaining an Effective and Resilient Oncology Careforce: Opportunities for Action. J Natl Cancer Inst. https://pubmed.ncbi.nlm.nih.gov/31868912/

2019

- Balogh, E.P., A.B. Bindman, S.G. Eckhardt, S. Halabi, R.D. Harvey, I. Jaiyesimi, R. Miksad, H.L. Moses, S.J. Nass, R.L. Schilsky, S. Sun, J.M. Torrente, K.E. Warren. 2019. Challenges and Opportunities to Updating Prescribing Information for Longstanding Oncology Drugs. The Oncologist 24: 1-7. https://theoncologist.onlinelibrary.wiley.com/, doi/10.1634/theoncologist.2019-0698.
- Takvorian, S.U., E. Balogh, S. Nass, V.L. Valentin, L. Hoffman-Högg, R.A. Oyer, R.W. Carlson, N.J. Meropol, L.K. Sheldon, L.N. Shulman. 2019. Developing and sustaining an effective and resilient oncology careforce: Opportunities for action, JNCI: Journal of the National Cancer Institute, djz239, https://doi.org/10.1093/jnci/djz239 https://academic.oup.com/jnci/advance-article/doi/10.1093/jnci/djz239/5685814.
- Kline, R. M., G. B. Rocque, E. A. Rohan, K. A. Blackley, C. A. Cantril, M. L. Pratt-Chapman, H. A. Burris, and L. N. Shulman. 2019. Patient navigation in cancer: the business case to support clinical needs. *Journal of Oncology Practice*. Epub ahead of print JOP.1900230. https://www.ncbi.nlm.nih.gov/pubmed/31509483.
- Lubejko, B. G., C. Cantril, L. H. Hogg, and L. Kennedy Sheldon. 2019. Novice oncology nurse navigator: core elements in establishing training needs and building on competencies. *Clinical Journal of Oncology Nursing* 23(4): 387-394. https://www.ncbi.nlm.nih.gov/pubmed/31322621.
- Nass, S. J., K. Elenitoba-Johnson, R. Nayar, M. Zutter, E. P. Balogh, R. L. Schilsky, M. Cohen, and H. Hricak. 2019. Improving cancer diagnosis and care: Patient access to high-quality oncologic pathology. *The Oncologist.* Epub ahead of print theoncologist.2019-0261. https://www.ncbi.nlm.nih.gov/pubmed/31366725.

**access date for all articles: February 13, 2020*

2019, *continued*

- Lopez, D., M. L. Pratt-Chapman, E. A. Rohan, L. K. Sheldon, K. Basen-Engquist, R. Kline, L. N. Shulman, and E. J. Flores. 2019. Establishing effective patient navigation programs in oncology. *Supportive Care in Cancer* 27(6):1985-1996. https://www.ncbi.nlm.nih.gov/pubmed/30887125.
- Nass, S. J., C. R. Cogle, J. A. Brink, C. P. Langlotz, E. P. Balogh, A. Muellner, D. Siegal, R. L. Schilsky, and H. Hricak. Improving cancer diagnosis and care: Patient access to oncologic imaging expertise. *Journal of Clinical Oncology* Epub ahead of print JCO.18.01970. https://www.ncbi.nlm.nih.gov/pubmed/31050908.

2018

- Kline, R. M., N. K. Arora, C. J. Bradley, E. R. Brauer, D. L. Graves, N. Buchanan Lunsford, M. S. McCabe, S. F. Nasso, L. Nekhlyudov, J. H. Rowland, R. M. Schear, and P. A. Ganz. Long-Term Survivorship Care After Cancer Treatment—Summary of a 2017 National Cancer Policy Forum Workshop. *JNCI: Journal of the National Cancer Institute* 110, no. 12: 1300-1310. https://www.ncbi.nlm.nih.gov/pubmed/30496448.
- Nass, S. J., M. Rothenberg, R. Pentz, H. Hricak, A. Abernethy, K. Anderson, A. W. Gee, R.D. Harvey, S. Piantadosi, M. M. Bertagnolli, D. Schrag, and R. L. Schilsky. Accelerating anticancer drug development–opportunities and trade-offs. *Nature Reviews Clinical Oncology* 15 (12): 777-786. https://www.ncbi.nlm.nih.gov/pubmed/30275514.
- Demark-Wahnefried, W., K. H. Schmitz, C. M. Alfano, J. R. Bail, P. J. Goodwin, C. A. Thomson, D. W. Bradley, K. S. Courneya, C. A. Befort, C. S. Denlinger, J. A. Ligibel, W. H. Dietz, M. R. Stolley, M. L. Irwin, M. M. Bamman, C. M. Apovian, B. M. Pinto, K. Y. Wolin, R. M. Ballard, A. J. Dannenberg, E. G. Eakin, M. M. Longjohn, S. D. Raffa, L. L. Adams-Campbell, J. S. Buzaglo, S. J. Nass, G. M. Massetti, E. P. Balogh, E. S. Kraft, A. K. Parekh, D. M. Sanghavi, G. S. Morris, and K. Basen-Engquist. 2018. Weight Management and Physical Activity throughout the Cancer Care Continuum. *CA: A Cancer Journal for Clinicians* 68(1):64–89. https://www.ncbi.nlm.nih.gov/pubmed/29165798.

2017

- Basen-Engquist, K., C. M. Alfano, M. Maitin-Shepard, C. A. Thomson, K. H. Schmitz, B. M. Pinto, K. Stein, D. S. Zucker, K. L. Syrjala, E. Fallon, C. Doyle, and W. Demark-Wahnefried. 2017. Agenda for Translating Physical Activity, Nutrition, and Weight Management Interventions for Cancer Survivors into Clinical and Community Practice. *Obesity* (Silver Spring) 25 Suppl 2:S9–s22. https://www.ncbi.nlm.nih.gov/pubmed/29086526.
- Smith, G. L., P. A. Ganz, J. E. Bekelman, S. J. Chmura, J. J. Dignam, J. A. Efstathiou, R. Jagsi, P. A. Johnstone, M. L. Steinberg, S. B. Williams, J. B. Yu, A. L. Zietman, R. R. Weichselbaum, and Y.-C. Shih. 2017. Promoting the Appropriate Use of Advanced Radiation Technologies in Oncology: Summary of a National Cancer Policy Forum Workshop. *International Journal of Radiation Oncology • Biology • Physics* 97(3):450–461. https://www.ncbi.nlm.nih.gov/pubmed/28011046.

2016

- Kirch, R., G. Reaman, C. Feudtner, L. Wiener, L. A. Schwartz, L. Sung, and J. Wolfe. 2016. Advancing a comprehensive cancer care agenda for children and their families: Institute of Medicine workshop highlights and next steps. *CA: A Cancer Journal for Clinicians* 66(5):398–407. https://www.ncbi.nlm.nih.gov/pubmed/27145249.

2015

- Nass, S. J., L. K. Beaupin, W. Demark-Wahnefried, K. Fasciano, P. A. Ganz, B. Hayes-Lattin, M. M. Hudson, B. Nevidjon, K. C. Oeffinger, R. Rechis, L. C. Richardson, N. L. Seibel, and A. W. Smith. 2015. Identifying and Addressing the Needs of Adolescents and Young Adults with Cancer: Summary of an Institute of Medicine Workshop. *Oncologist* 20(2):186–195. https://www.ncbi.nlm.nih.gov/pubmed/25568146.

2014

- Bertagnolli, M. M., R. Canetta, and S. J. Nass. 2014. Expanding Public-Private Collaborations to Enhance Cancer Drug Development: A Report of the Institute of Medicine's Workshop Series, "Implementing a National Cancer Clinical Trials System for the 21st Century." *Oncologist* 19(11):1179-1185. https://www.ncbi.nlm.nih.gov/pubmed/25326161.
- Balogh, E. P., C. Dresler, M. E. Fleury, E. R. Gritz, T. J. Kean, M. L. Myers, S. J. Nass, B. Nevidjon, B. A. Toll, G. W. Warren, and R. S. Herbst. 2014. Reducing Tobacco-Related Cancer Incidence and Mortality: Summary of an Institute of Medicine Workshop. *Oncologist* 19(1):21–31. https://www.ncbi.nlm.nih.gov/pubmed/24304712.
- Ferrell, B. R., T. J. Smith, L. Levit, and E. Balogh. 2014. Improving the Quality of Cancer Care: Implications for Palliative Care. *Journal of Palliative Medicine* 17(4):393–399. https://www.ncbi.nlm.nih.gov/pubmed/24548217.

2013

- Ramsey, S. D., P. A. Ganz, V. Shankaran, J. Peppercorn, and E. Emanuel. 2013. Addressing the American Health-Care Cost Crisis: Role of the Oncology Community. *JNCI: Journal of the National Cancer Institute* 105(23):1777–1781. https://www.ncbi.nlm.nih.gov/pubmed/24226096.
- Balogh, E. P., P. B. Bach, P. D. Eisenberg, P. A. Ganz, R. J. Green, J. C. Gruman, S. J. Nass, L. N. Newcomer, S. D. Ramsey, J. E. Schottinger, and Y. T. Shih. 2013. Practice-Changing Strategies to Deliver Affordable, High-Quality Cancer Care: Summary of an Institute of Medicine Workshop. *Journal of Oncology Practice* 9(6s):54s–59s. https://www.ncbi.nlm.nih.gov/pubmed/29431037.

2012

- Demark-Wahnefried, W., E. A. Platz, J. A. Ligibel, C. K. Blair, K. S. Courneya, J. A. Meyerhardt, P. A. Ganz, C. L. Rock, K. H. Schmitz, T. Wadden, E. J. Philip, B. Wolfe, S. M. Gapstur, R. Ballard-Barbash, A. McTiernan, L. Minasian, L. Nebeling, and P. J. Goodwin. 2012. The Role of Obesity in Cancer Survival and Recurrence. *Cancer Epidemiology, Biomarkers & Prevention* 21(8):1244–1259. https://www.ncbi.nlm.nih.gov/pubmed/22695735.
- LoRusso, P. M., R. Canetta, J. A. Wagner, E. P. Balogh, S. J. Nass, S. A. Boerner, and J. Hohneker. 2012. Accelerating Cancer Therapy Development: The Importance of Combination Strategies and Collaboration. Summary of an Institute of Medicine Workshop. *Clinical Cancer Research* 18(22):6101–6109. https://www.ncbi.nlm.nih.gov/pubmed/23065428.

2011

- Nass, S. J., E. Balogh, and J. Mendelsohn. 2011. A National Cancer Clinical Trials Network: Recommendations from the Institute of Medicine. *American Journal of Therapeutics* 18(5):382–391. https://www.ncbi.nlm.nih.gov/pubmed/21326081.
- Balogh, E. P., P. A. Ganz, S. B. Murphy, S. J. Nass, B. R. Ferrell, and E. Stovall. 2011. Patient-Centered Cancer Treatment Planning: Improving the Quality of Oncology Care. Summary of an Institute of Medicine Workshop. *Oncologist* 16(12):1800–1805. https://www.ncbi.nlm.nih.gov/pubmed/22128118.

2010

- Altshuler, J. S., E. Balogh, A. D. Barker, S. L. Eck, S. H. Friend, G. S. Ginsburg, R. S. Herbst, S. J. Nass, C. M. Streeter, and J. A. Wagner. 2010. Opening up to Precompetitive Collaboration. *Science Translational Medicine* 2(52):52cm26. https://www.ncbi.nlm.nih.gov/pubmed/20926831.

FORUM ON CYBER RESILIENCE

DIVISION ON ENGINEERING AND PHYSICAL SCIENCES

ABOUT THE FORUM

The Forum on Cyber Resilience serves as an independent, trusted venue in which experts from industry, academia, and government can work collaboratively to explore emerging critical challenges related to the security, trustworthiness, and resilience of the nation's computing, communications systems, and critical infrastructures.

Blending expertise in technology, policy, national security, and the law, the Forum convenes senior representatives and serves both as a readily available source of insight and expertise and as a body committed to anticipating and thinking about future trends. Forum activities inform stakeholders through convenings, dialogues, and published workshop summaries and through engagements with consensus study committees.

OUR ACTIVITIES

The Forum convenes a multidisciplinary group of experts with perspectives spanning research, practice, technology, and policy, to address issues including cybersecurity and trustworthiness; stakeholder values, such as privacy, transparency, adaptability, and usability; and preparation, response, and recovery in the face of targeted disruptions as well as natural or technical disasters.

The Forum meets three times annually to plan and execute workshops and supplementary activities. The Forum regularly hosts workshops, symposia, panels, talks, and other events that bring together experts and practitioners from industry, academia, and the government to consider issues related to cybersecurity and cyber resilience and their implications for policy and practice. In a space free from partisan pressures and preset agendas, participants share their own research, insights, and perspectives and also look beyond them—making connections within and across disciplines, sharpening questions, sparking new ideas, and exploring possible solutions.

Some workshops focus on specialized areas, while others tackle broad questions. When necessary, we can swiftly gather the nation's top minds to address matters of urgent importance. When there is a need for ongoing dialogue, National Academies' roundtables and forums—which are organized around a topic—offer stakeholders an opportunity to build relationships and unravel complicated issues over time.

For more information, visit our website:
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NASEM
Opportunities and Challenges for Using Digital Health Applications in Oncology:
A Virtual Workshop
July 13-14, 2020

Medical Malpractice Considerations and Risk Mitigation Strategies in Implementing Digital Health Applications

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MaineHealth

I. Introduction

The COVID-19 pandemic has reshaped healthcare delivery, causing a rapid and unprecedented shift toward virtual care and clearly demonstrating that digital health technologies should no longer be considered only an ancillary or complementary treatment option. A myriad of digital health applications has permeated the healthcare sector and offer the following benefits: (i) access to affordable and quality healthcare via an internet connection facilitating patient visits in rural areas or in situations where inperson visits are not convenient or currently available; (ii) enables patients to make informed decisions about their own health through proactive monitoring and to seek professional medical advice in a timely manner if such monitoring identifies any alerts; (iii) permits the management of chronic conditions outside of traditional healthcare settings; (iv) leads to greater patient empowerment and adherence to treatment since patients receive information in real time; and (v) facilitates the collection of data on users' health markers which can be utilized to identify connections between people's lifestyles and medical conditions thereby improving the public health.

The digital health market is blurring the lines between what typically is viewed as 'medical-grade' and 'consumer' digital health technology. For example, Apple's recent addition of an electrocardiogram function to the latest model of the Apple Watch expands the functionality of a consumer device to perform a medical function that potentially could identify a previously undiagnosed cardiac condition. Similarly, medical devices increasingly are gaining digital functionality. Medtronic has created a mobile health application that allows individuals with internet-enabled pacemakers to share data via their smartphones with their clinicians. The technological convergence of consumer digital health technologies with professional medical equipment raises questions about the extent to which patients and clinicians can rely upon 'consumer-grade' technologies, particularly when such technologies are not cleared or approved by the Food and Drug Administration (FDA).

Certain digital health applications such as consumer-based mobile telemetry applications can be useful in the management of oncology patients who may suffer heart rhythm irregularities. Individuals with a history of certain cancers have been reported to have an over two-fold risk of developing atrial fibrillation compared to the general population.[1] Additionally, some cancer therapies can cause or exacerbate damage to the patient's heart and the cardiovascular system including high blood pressure, abnormal heart rhythms and heart failure.[2] To illustrate how digital innovation in the healthcare sector can create

[1] *See* Patients with Certain Cancers May Be at a Higher Risk for Atrial Fibrillation, THE ASCO POST, *available online at* https://www.ascopost.com/news/march-2020/patients-with-certain-cancers-may-be-at-a-higher-risk-for-atrial-fibrillation/#:~:text=People%20with%20a%20history%20of,(Abstract%201216%2D235).

[2] *See* Heart Problems: Investigating the Cardiac Side Effects of Cancer Treatments, NATIONAL CANCER INSTITUTE BLOG, *available online at* https://www.cancer.gov/news-events/cancer-currents-blog/2018/cancer-treatment-heart-side-effects.

potential medical malpractice exposure, this presentation will utilize consumer-based mobile telemetry applications as an example.

II. Risk Management Strategies to Minimize Medical Malpractice Exposure

A. *There can be limitations in the recording quality and automatic interpretation of telemetry data collected by consumer-based mobile telemetry applications.*

- *Within what parameters will a health care provider use such mobile telemetry applications?* Consistent with principles of informed consent, a healthcare provider should review telemetry strips obtained from a patient's use of certain consumer-based mobile telemetry applications subject to the patient's agreement to and compliance with certain conditions imposed by the provider. The patient's consent and any conditions under which a provider will interpret such telemetry strips should be memorialized in a consent to treat form and/or patient agreement signed by the patient and included in the patient's electronic health record. An example of a Patient Agreement for Use of Mobile Telemetry Applications is included in Exhibit A. A provider should determine whether he or she is comfortable relying upon the telemetry strip to order further diagnostic studies or to render a definitive diagnosis and develop a treatment plan based upon the recording quality of the telemetry data or other limitations of the mobile telemetry application.

- *For what patient population is the use of mobile telemetry applications acceptable given the limitations of such applications?* In determining the patient population for which a healthcare provider will review mobile telemetry strips, a clinician should specify that an individual must be a current patient of the practice and have been evaluated within a recent period (*e.g*., the last 1-2 years) as opposed to using such applications for new patients with whom the provider is not familiar and for which no patient history is available.

- *Under what circumstances will a healthcare provider review telemetry strips from a mobile telemetry application?* A provider should inform patients when he or she will be available to review mobile telemetry strips, particularly since the receipt of such data may not be part of the clinician's usual work flow. Will the provider review such telemetry strips only on a non-urgent basis during regular office hours, or will he or she perform on-call interpretations as well? If the patient is feeling unwell outside of regular office hours, then the patient should be encouraged to seek urgent medical care at an emergency department since a provider may not be able to immediately review a mobile telemetry strip that a patient transmits to him or her.

- *Telemetry strips recorded through mobile telemetry applications and sent to a healthcare provider for review may have artifact or other issues and thus not be able to be accurately interpreted.* The clinician should reserve the right to request that the patient undergo a repeat electrocardiogram either by using a Holter monitor at home or undergoing this procedure on site at the medical practice or hospital if he or she is not comfortable relying on the mobile telemetry strip.

- *Has the device been 'cleared' or 'approved' by the FDA?* Class I (low risk) and Class II (moderate risk) medical devices usually are 'cleared' by the FDA, which means the manufacturer can demonstrate that its product is substantially equivalent to another similar legally marketed device that already has obtained FDA clearance or approval (*i.e*., a predicate). If a medical device has been 'approved' by the FDA, then this means that the

agency has determined that the benefits of the product outweigh the known risks for the intended use. To obtain FDA approval, manufacturers must submit a premarket approval application as well as clinical testing results in order to obtain agency approval. FDA approval usually is mandatory to market or sell products within the United States that may pose a significant risk of injury or illness, but also can benefit an individual's health such as prescription medications, over-the-counter medications, vaccines and Class III (high risk) medical devices.[3] With FDA clearance or approval, providers are more likely to trust the data generated by consumer devices and feel comfortable in relying upon such data for diagnosis and treatment purposes.

B. ***The mobile telemetry application is licensed by the patient, utilized at the patient's discretion and may not be used by the patient in accordance with the instructions.***

- *It is important for patients to understand that the healthcare provider is not responsible for the quality, accuracy and reliability of the mobile telemetry recording and the automatic interpretation*. Moreover, the clinician cannot ensure that such mobile health applications do not contain software 'bugs' or become infected with malware. The provider further cannot be expected to 'trouble shoot' a patient's use of mobile telemetry applications or any connectivity issues with the medical practice's or hospital's e-mail server that the patient may experience in transmitting the telemetry recording to the clinician. These issues should be addressed in the consent to treat form and/or patient agreement.

C. ***Patient data either generated by or collected by a digital health application typically is not automatically included in the patient's electronic health record.***

- *Healthcare providers need to work with their Information Services Departments to develop a work flow for telemetry strips recorded through mobile telemetry applications to be incorporated into the patient's electronic health record if they plan to rely upon this information for diagnosis and treatment purposes.* Additionally, patient symptoms at the time the mobile telemetry application is triggered should be recorded within the application if such functionality is available and included along with the telemetry strip, or noted separately by the patient and communicated to the provider.

D. ***A patient's insurance may not cover the healthcare provider's interpretation of telemetry strips recorded through mobile telemetry applications.***

- *The provider should inform patients that he or she will submit charges for the review of the mobile telemetry strips to the patient's insurance carrier, but that such interpretations may not be a covered service and the patient may incur out-of-pocket expenses.* Moreover, reimbursement for using certain artificial intelligence (AI)-enabled technology is uncertain at this point in time. The patient further should be advised to check with his or her insurance carrier regarding any questions regarding insurance coverage for the interpretation of telemetry strips recorded through consumer-based mobile telemetry applications.

[3] *See* 21 C.F.R. Part 814 (Premarket Approval of Medical Devices) and Part 860 (Medical Device Classification Procedures).

E. Mobile health applications typically collect a significant amount of personal health information.

- *The developers of mobile health applications may use or disclose a patient's personal health information without the patient's prior knowledge or authorization since such developers currently are not subject to the HIPAA Privacy Standards.* Healthcare providers who recommend the use of mobile telemetry applications should advise patients to carefully review the vendor's terms and conditions of use to ensure that the patient is comfortable with the manner in which his or her personal health information may be used and/or disclosed to third parties.

F. AI-enabled digital health technologies raise a number of novel legal issues.

- *It currently is unclear whether or not a healthcare provider has a duty to disclose the risks of the AI-enabled digital health technologies and alternatives to the patient.* For example, there could be a risk of bias from the particular data and/or the manner in which the AI-enabled technology was developed because the data used to 'train' the system may not be sufficiently diverse or may have unique characteristics. While such bias may be unintentional, it still presents an important source of risk when AI-enabled technologies are used later with other populations. Additionally, healthcare providers may not have sufficient technical knowledge to adequately explain the risks and benefits of certain AI-enabled technologies to patients so that they can make an informed decision about the use of such technologies in their diagnosis and treatment. What is the ongoing duty of physicians to oversee AI-enabled technology used in their medical practices? Does the AI-enabled technology require supervision by or input from a physician and thus augment clinical decision-making, or does it supplant a physician's independent medical judgment? Finally, AI-enabled technologies pose potentially greater risk to patients since an error can be replicated across a greater number of patients than that of a human clinician error in judgment.

III. Conclusion

It is unclear how current theories of medical malpractice liability will apply to claims involving emerging digital health technologies because the law typically trails advances in technology. Traditionally, medical malpractice is based on negligence which is defined as any act or omission by a clinician during the treatment of a patient that deviates from accepted norms of practice and causes injury to the patient. The standard of care in medical malpractice actions -- usually a national or community-based standard relating to what is customary practice among physicians in the same specialty in similar settings -- generally is established through expert witness testimony.[4] In contrast, if a medical device or certain equipment is responsible for the patient's injury, then principles of product liability apply with its strict liability standard for manufacturing defects, design defects and failure to warn of such defects.

[4] Jurisdictions differ as to the standard of care employed in a medical malpractice action. The national standard of care requires a doctor to use the degree of skill and care of a reasonably competent practitioner in his field under same or similar circumstances. The community-based or locality standard requires a physician to have the reasonable caliber of skill and knowledge that is generally possessed by surgeons and physicians in the locality where he or she practices. The respectable minority rule provides that where the physician did not follow the same course of therapy that other doctors would have followed, he can show that his course is accepted by a respectable minority of practitioners. Given the implementation of national standards for medical education and the universal availability of online guidance and evidence, there has been increasing support for a shift to a national standard of care. *See* Michelle Huckaby Lewis et al., *The Locality Rule and the Physician's Dilemma*, 297 J. Am. Med. Ass'n. 2633, 2634 (2007).

As the use of emerging technologies becomes more common, the standard of care in medical malpractice actions likely will undergo change because certain technologies, such as an AI-enabled diagnostic tool, may supplant rather than augment a clinician's professional judgment or function. In determining legal liability, it presently is unclear whether the use of new digital health technologies in patient care that results in injury to a patient will be evaluated under the traditional negligence standard applied in medical malpractice claims or by the product liability doctrine.[5] In determining whether a negligence standard or product liability will apply, courts likely will use the existing legal framework and first determine if the emerging technology is a medical device or a medical service or procedure. Historically, medical devices (mostly hardware-based) have been regulated by the FDA while the practice of medicine has been regulated by state law. With the advent of software as a medical device (SaMD) that is intended to be used for one or more medical purposes without being part of a hardware medical device, this regulatory distinction has become blurred. In 2016, Congress enacted the 21st Century Cures Act[6] (Cures Act) which contains important changes to the medical device provisions of the Federal Food, Drug, and Cosmetic Act (FDCA) and clarifies the FDA's jurisdiction over digital health products. Section 3060 of the Cures Act expressly excludes from the FDCA's definition of medical device five distinct categories of software or digital health products.[7] To clarify its interpretation of Section 3060, the FDA issued draft guidance on December 8, 2017[8]. This draft guidance discusses each part of the exclusion and provides instruction regarding how software may permit independent review by a healthcare practitioner.[9]

As the regulation of digital health technologies continues to evolve, this may affect whether a negligence standard or product liability will apply in the context of a medical malpractice claim. Moreover,

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[5] *See* Scott Bennett & Leeann Habte, *Artificial Intelligence in Health Care: Welcome to the Machine*, AHLA CONNECTIONS, Dec. 2018, at 16, 18–19.

[6] Pub. L. No: 114-255 (December 13, 2016). *See also* Section III. Interpretation of Criteria in Section 520(o)(1)(E) of the FD&C Act, Clinical and Patient Decision Support Software, Draft Guidance for Industry and Food and Drug Administration (December 8, 2017), p.7 *available online at* https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587819.pdf

[7] A medical device is defined in Section 201(h) of the Food Drug & Cosmetic Act as "...an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is either: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; (ii) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or (iii) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes." *See* 21 C.F.R. Subchapter H - MEDICAL DEVICES.

[8] *See* Clinical and Patient Decision Support Software, Draft Guidance for Industry and Food and Drug Administration (December 8, 2017) *available online at* https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587819.pdf.

[9] On April 2, 2019, the FDA also published a discussion paper, *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)- Discussion Paper and Request for Feedback*, that describes the FDA's potential approach to pre-market review for artificial intelligence and machine learning-driven software modifications. *See* Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback (April 2, 2019), *available online at* https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/SoftwareasaMedicalDevice/UCM635052.pdf. The proposed regulatory oversight would enable the FDA and manufacturers to evaluate and monitor a software product from its pre-market development to post-market performance thereby embracing iterative improvement that would allow for modifications to be made from real-world learning and adaptation, while assuring patient safety. *Id*.

establishing whether the clinician who employed the AI-enabled diagnostic tool or the health IT vendor and/or developer is at fault in the event of harm to a patient, or the degrees of comparative negligence among the clinician, vendor and developer will be complicated given the myriad of functionalities and the blurring of boundaries between the tasks that are performed by the clinician and the extent to which the AI-enabled diagnostic tool is substituting for a clinician's professional judgment or function. As AI algorithms improve and clinicians increasingly utilize this technology for diagnosing and clinical decision-making purposes, the traditional malpractice standard of negligence may become more difficult to apply. AI algorithms can change in unexpected ways making it difficult to apply traditional concepts of foreseeable harm and human causation. Moreover, it may be impossible to replicate the negative result because AI-enabled technology has learned and changed.

Given the uncertainties regarding the standard of care and how current theories of medical malpractice liability will apply to claims involving emerging digital health technologies, it is prudent for healthcare providers to employ risk mitigation strategies in implementing such technologies.

Exhibit A

This Patient Agreement for Use of Mobile Telemetry Applications should not be construed as legal advice and does not address all possible legal and other issues that may arise by clinicians incorporating digital health applications into their medical practices. Each health care provider is unique and will need to consider its particular circumstances, and should obtain the advice of an experienced attorney in assessing its specific needs.

Patient Agreement for Use of Mobile Telemetry Applications

Patient Name: _____ Date: _____

DOB: _____ MR#: _____

Consistent with principles of patient-centered care, <Hospital/Medical Practice> will review telemetry strips obtained from a patient's use of certain consumer-based mobile telemetry applications subject to the terms and conditions described below. You understand that there are known limitations in the recording quality and automatic interpretation of telemetry data collected by consumer-based mobile telemetry applications. If you wish to utilize such applications, then you must agree to and comply with the following terms and conditions:

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1. You must be a current patient of <Hospital/Medical Practice> and have been evaluated within the last two (2) years in order for mobile telemetry strips to be reviewed by the <Hospital/Medical Practice>.

2. <Hospital/Medical Practice> will review telemetry strips from certain mobile telemetry applications only on a non-urgent basis during regular office hours. No on-call interpretations will be performed. If you are feeling unwell, we encourage you to seek urgent medical care at a local emergency department.

3. All mobile telemetry applications are licensed by you and utilized at your discretion. <Hospital/Medical Practice> is not responsible for the quality, accuracy and reliability of the telemetry recording and its automatic interpretation. Moreover, <Hospital/Medical Practice> cannot ensure that such applications do not contain software 'bugs' or become infected with malware. <Hospital/Medical Practice> further cannot 'trouble shoot' your use of mobile telemetry applications or any connectivity issues that you may experience with the <Hospital's/Medical Practice's> e-mail server.

4. Telemetry strips recorded through mobile telemetry applications and sent to <Hospital/Medical Practice> for review may have artifact or present other issues, and thus may not be able to be interpreted by the <Hospital/Medical Practice>. The <Hospital/Medical Practice> reserves the right to request that you undergo a repeat electrocardiogram either by using a Holter monitor at home or undergoing this procedure on site at the <Hospital/Medical Practice>.

5. Not all mobile telemetry strips are in a format that can be interpreted through <Hospital's/Medical Practice's> information system, and the <Hospital/Medical Practice> reserves the right not to review telemetry strips collected by certain mobile telemetry applications that are not compatible with its clinical information systems. Generally, <Hospital/Medical Practice> needs tracings to be submitted in ***.pdf*** format. In such instances, the <Hospital/Medical Practice> reserves the right to request that you undergo a repeat electrocardiogram either by using a Holter monitor at home or undergoing this procedure on site at the <Hospital/Medical Practice>.

6. You understand and agree that telemetry strips recorded through mobile telemetry applications and e-mailed to <Hospital/Medical Practice> for review by the <Hospital/Medical Practice> will become part of your permanent electronic health record.

7. You will be assessed a charge for the review of ***each*** transmission of a telemetry strip by <Hospital/Medical Practice>. <Hospital/Medical Practice> will submit such charges to your insurance carrier, but such interpretations may not be a covered service and you may incur out-of-pocket expenses. It is your responsibility to check with your insurance carrier regarding any questions regarding coverage for the interpretation of telemetry strips recorded through mobile telemetry applications.

8. You agree to use the mobile telemetry application in accordance with the product's instructions to ensure the best available electrocardiogram. You further agree to record your symptoms at the time the mobile telemetry application is triggered within the application if such functionality is available, or to note your symptoms separately and include this information along with the telemetry strip for review by the <Hospital/Medical Practice> when e-mailing this information to the <Hospital/Medical Practice>.

9. You agree to send telemetry strips along with a description of your symptoms at the time that the mobile telemetry application is triggered to ***<Hospital's/Medical Practice's e-mail address>*** in ***.pdf*** format.

10. You will ***not*** receive any correspondence from <Hospital/Medical Practice> in response to e-mails requesting review of telemetry strips other than an acknowledgement of receipt of the e-mail. You should call the <Hospital/Medical Practice> at (###) ###-### or utilize the MyChart patient portal for any questions relating to the interpretation.

11. You should be aware that mobile health applications typically collect a significant amount of personal health information which may not be protected by the same laws applicable to similar information collected in your healthcare provider's office. The developers of these applications may use or disclose your personal health information to third parties without your prior knowledge or authorization. You should carefully review the mobile health application's terms and conditions of use to ensure that you are comfortable with the manner in which your personal health information may be used or disclosed to third parties.

12. You acknowledge that you have reviewed this Agreement, understand your obligations and the potential limitations of obtaining a professional medical interpretation of an electrocardiogram obtained from a mobile telemetry application, and have had the opportunity to ask questions.

_____ _____

Signature of Patient or Authorized Representative Date

_____ _____

Signature of Witness Date

Drug Research and Development for Adults Across the Older Age Span

A Virtual Workshop

August 5-6 2020

10:00 a.m. – 3:00 p.m. (ET)

ZOOM WEBINAR REGISTRATION:
https://nasem.zoom.us/webinar/register/WN_1IN7kZ-ESdWppXPNGVPPQw

Agenda

Despite the widespread recognition of the "graying of America," and the need for health care among older adults, there is a dearth of information about the appropriate use of drugs in this population. Older adults are vastly underrepresented in clinical trials. Yet older adults have higher rates of comorbidities and polypharmacy than the general population, and are the majority users of many medications. Additionally, age-related physiological and pathological changes, particularly for adults 80+, can lead to significant differences in the pharmacokinetic and pharmacodynamics of a given drug compared to the general population. There is a void in evidence-based information for making informed decisions on how to best optimize care for older adults, particularly those 80+.

This public workshop will provide a venue for stakeholders to discuss the challenges and opportunities in drug research and development (R&D) for older adult populations, explore barriers that impede safety and efficacy studies in these populations, and share lessons learned for better understanding the clinical pharmacology for 65+ and 80+ populations.

The workshop will feature invited presentations and discussions to:

- Review the current landscape of drug R&D for 65+ and 80+ populations across public and private sectors;
- Consider medication issues for older adult populations (e.g. dosage forms, adherence, polypharmacy, differences in PK/PD);
- Explore methodologies that are currently used or could be implemented to study differences in pharmacology for older adult populations (e.g. minimal sampling);
- Examine barriers to conducting clinical research for 65+ and 80+ populations (e.g. funding, data, co-morbidity, polypharmacy, recruitment, access); and
- Explore approaches to engage 65+ and 80+ populations in clinical research and strategies generate evidence-based information on how to best optimize treatment for older adults.

DAY 1: August 5, 2020

10:00 a.m. **Welcome and opening remarks**
JAMES APPLEBY, *Workshop Chair*
Chief Executive Officer
The Gerontological Society of America

SESSION I INCLUSION OF OLDER ADULTS IN CLINICAL TRIALS: AN EVOLVING LANDSCAPE

Session Objectives:

- Review the current landscape of drug R&D for 65+ and 80+ populations across public and private sectors;
- Consider medication issues for older adult populations (e.g., dosage forms, adherence, polypharmacy, differences in PK/PD);
- Examine barriers to conducting clinical research for 65+ and 80+ populations (e.g., funding, data, co-morbidity, polypharmacy, recruitment, access).

10:10 a.m. **Introduction by session moderator**
JERRY GURWITZ
Executive Director, Division Chief of Geriatric Medicine
Meyers Primary Care Institute, UMass Memorial Medical Center

10:15 a.m. **Knowledge gaps & issues unique to older adults**
ROSANNE M. LEIPZIG
Professor of Geriatrics and Palliative Medicine
Icahn School of Medicine at Mount Sinai

Age-related changes that impact drug metabolism
GEORGE A. KUCHEL
Travelers Chair in Geriatrics and Gerontology, Professor of Medicine
University of Connecticut Center on Aging

Barriers to conducting clinical trials that include older adults
NIH perspective
MARIE BERNARD
Deputy Director
National Institutes of Health, National Institute on Aging

Industry perspective
KATHERINE DAWSON
Senior Vice President of the Therapeutics Development Group
Biogen

11:00 a.m. *Moderated panel discussion*

11:30 a.m. **BREAK**

SESSION II CONCOMITANT ILLNESS AND POLYPHARMACY: OVERCOMING KEY BARRIERS

Session Objectives:

- Explore methodologies that are currently used or could be implemented to study differences in pharmacology for older adult populations (e.g., minimal sampling);

11:40 a.m. **Opening remarks by panel moderator**
JONATHAN WATANABE
Professor of Clinical Pharmacy, Associate Dean of Assessment and Quality
University of California Irvine Samueli College of Health Sciences

11:45 a.m. **Clinical trial considerations [Panel]**
Inclusion / exclusion criteria and trial design
HEATHER ALLORE
Professor of Medicine (Geriatrics) and Biostatistics
Yale University

Organ function criteria expansion
STUART M. LICHTMAN
Medical Oncologist
Memorial Sloan Kettering Cancer Center

FDA perspective
RAJESHWARI SRIDHARA
Director of the Division of Biometrics V
U.S. Food and Drug Administration, Center for Drug Evaluation and Research

Ethics perspective
JASON KARLAWISH
Professor of Medicine
University of Pennsylvania Perelman School of Medicine

12:30 p.m. *Moderated panel discussion*

1:00 p.m. **BREAK**

1:20 p.m. **Opening remarks by panel moderator**
ROBERT TEMPLE
Deputy Center Director for Clinical Science, Office of New Drugs
U.S. Food and Drug Administration, Center for Drug Evaluation and Research

Alternative study approaches [Panel]
Adaptive design
SCOTT BERRY
Co-Founder and President
Berry Consultants

Internet-based drug trials
STEVEN R. CUMMINGS
Research Scientist
California Pacific Medical Center Research Institute

Quantitative systems pharmacology models: Mechanistic science perspective
CHRISTINA FRIEDRICH
Chief Engineer
Rosa & Co.

Clinical trial simulation
N. SETH BERRY
Senior Director, Decision Sciences Group
IQVIA

Real world trials
STEVEN CHEN
Associate Dean for Clinical Affairs
University of Southern California School of Pharmacy

2:20 p.m. *Moderated panel discussion*

DAY 1 REFLECTIONS

2:50 p.m. **Closing remarks**
JAMES APPLEBY, *Workshop Chair*
Chief Executive Officer
The Gerontological Society of America

3:00 p.m. **ADJOURN WORKSHOP DAY 1**

DAY 2: August 6, 2020

10:00 a.m. **Welcome and overview of Day 1**
JAMES APPLEBY, *Workshop Chair*
Chief Executive Officer
The Gerontological Society of America

SESSION III THE ERA OF COVID-19 AND BEYOND

Session Objectives:

- Explore methodologies that are currently used or could be implemented to study differences in pharmacology for older adult populations (e.g., minimal sampling);
- Explore approaches to engage 65+ and 80+ populations in clinical research and strategies generate evidence-based information on how to best optimize treatment for older adults.

10:10 a.m. **Opening remarks by panel moderator**
DEBORAH COLLYAR
President
Patient Advocates in Research

10:15 a.m. **Older adult outreach & networking strategies**
JONATHAN TOBIN
President/CEO
Clinical Directors Network

Barbershop-based outreach programs: Case study
CIANTEL BLYLER
Clinical Research Pharmacist
Cedars-Sinai Medical Center

Patient perspective
SUSAN STRONG
Principal
The Strong Group

Caregiver perspective
LAUREL PRACHT
Research Patient Advocate and Patient Representative
NCI Symptom Management and Health-Related Quality of Life Steering Committee

Education for older adults and healthcare practitioners
STEVEN ROTHSCHILD
Vice Chairperson, Department of Preventive Medicine
Rush Medical College

11:15 a.m. *Moderated panel discussion*

11:45 a.m. **BREAK**

12:00 p.m. **Opening remarks by panel moderator, European perspective**
SVEN STEGEMANN
Professor for Patient Centric Drug Development and Manufacturing
Graz University of Technology

Lessons learned from COVID-19
U.S. regulatory changes
HARPREET SINGH
Division Director (Acting)
U.S. Food and Drug Administration, Division of Oncology 2

Infectious disease perspective
JOHN POWERS
Senior Medical Scientist
Leidos Biomedical Research

Telehealth / Physician perspective
ERIKA RAMSDALE
Assistant Professor
University of Rochester Medical Center

Digitization of medicine
ERIC TOPOL
Founder and Director
Scripps Research Translational Institute

Patient perspective
BEVERLY CANIN
Member
Cancer and Aging Research Group

1:00 p.m. *Moderated panel discussion*

1:30 p.m. **BREAK**

1:45 p.m. **Reflections: Looking forward to the future**

Session moderator
JAMES APPLEBY, *Workshop Chair*
Chief Executive Officer
The Gerontological Society of America

1:50 p.m. AMY ABERNETHY
Principle Deputy Commissioner – Office of the Commissioner
U.S. Food and Drug Administration

ROBERT CALIFF
Head of Clinical Policy and Strategy
Verily and Google Health

MARIE BERNARD
Deputy Director
National Institutes of Health, National Institute on Aging

2:20 p.m. *Moderated panel discussion*

2:50 p.m. **Next Steps**
JAMES APPLEBY, *Workshop Chair*
Chief Executive Officer
The Gerontological Society of America

3:00 p.m. **ADJOURN WORKSHOP DAY 2**

NATIONAL CANCER POLICY FORUM

Addressing the Adverse Consequences of Cancer Treatment

A National Cancer Policy Forum Workshop
Hosted in Collaboration with the Forum on Aging, Disability, and Independence

November 9-10, 2020
Virtual

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 array of short- and long-term toxicities and adverse effects that patients may experience as a result of cancer treatment and consider options to improve quality of life for cancer survivors and their families by addressing these adverse consequences. The workshop will feature invited presentations and panel discussions on topics that may include:

- An overview of the physical and mental health risks and socioeconomic consequences of cancer diagnosis and treatment, including unique considerations for different patient populations (e.g., children or older adults).
- Strategies to better accrue data on short- and long-term effects of cancer and cancer treatment, as captured by patient-reported outcome measures, clinician input, or other methods.
- Opportunities to redesign cancer treatment approaches to reduce short- and long-term toxicities without compromising treatment effectiveness, as well as strategies to mitigate toxicities that may occur.
- Patient engagement in treatment decision-making and tools to aid their assessment of the various risk/benefit tradeoffs.
- System-level interventions, best practices and low tech/low cost approaches to prevention, surveillance, and mitigation of cancer treatment–related toxicities and adverse effects.
- Opportunities to overcome the challenges that prevent uptake and dissemination of evidence-based approaches to address treatment-related toxicities and adverse effects.

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
Cathy Bradley, PhD, University of Colorado Cancer Center *(Co-Chair)*
Lisa Kennedy Sheldon, PhD, APRN, AOCNP®, FAAN, Oncology Nursing Society *(Co-Chair)*
Smita Bhatia, MD, MPH, University of Alabama at Birmingham
Julie Bynum, MD, MPH, University of Michigan
Gwen Darien, BA, Patient Advocacy and Engagement
Lori Hoffman Hōgg, MS, RN, CNS, AOCN, Department of Veterans Affairs
Samir N. Khleif, MD, Georgetown University Medical Center
Wui-Jin Koh, MD, National Comprehensive Cancer Network
J. Leonard Lichtenfeld, MD, MACP, American Cancer Society
Randall A. Oyer, MD, Lancaster General Penn Medicine
Lawrence N. Shulman, MD, MACP, FASCO, University of Pennsylvania

Improving the Evidence Base for Treatment Decision Making for Older Adults with Cancer: A Collaborative Workshop

National Cancer Policy Forum
Forum on Drug Discovery, Development, and Translation
Forum on Aging, Disability, and Independence

Workshop Date TBD
Sponsor: Food and Drug Administration

Statement of Task

An ad hoc planning committee will plan and host a 1.5-day public workshop to examine challenges and opportunities to improve the evidence base for treating older adults with cancer. The workshop will feature invited presentations and panel discussions on topics such as:

- The root causes that limit enrollment of older adults in clinical trials for oncology (and other disciplines such as cardiology and pulmonology), and strategies to mitigate those barriers;
- Strategies for inclusion of older adults in early phase studies (e.g., pharmacokinetic, pharmacodynamic, and in vitro studies that describe dose-response, concentration-response, and drug-drug and drug-disease interactions) that can inform the development of later phase studies;
- Clinical trial design and analysis strategies that could encourage and facilitate enrollment of older adults in cancer clinical trials (e.g., decentralization of clinical trial sites, broadening eligibility criteria, and offering caregiver support);
- Opportunities to incorporate geriatric assessments and patient reported outcomes into clinical trial designs; and
- Strategies to collect real world data via observational studies or registries to improve the collection of postmarket safety and efficacy data on newly approved drugs.

The planning committee will develop the agenda for the workshop sessions, select and invite speakers and panelists, 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 Pending