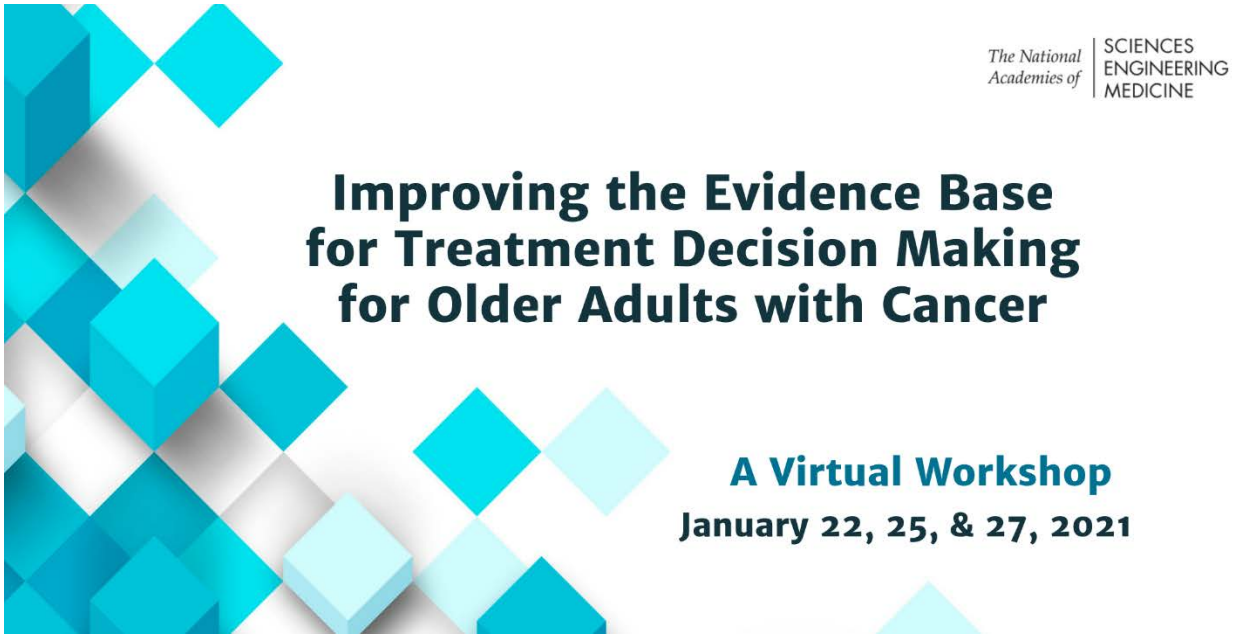
Improving the Evidence Base for Treatment Decision Making for Older Adults with Cancer

A Collaborative Workshop:
National Cancer Policy Forum
Forum on Aging, Disability, and Independence
Forum on Drug Discovery, Development, and Translation



Webcast:

- **Friday, January 22, 2021: 1:00 pm – 4:30 pm ET**
  - https://www.nationalacademies.org/event/01-22-2021/improving-the-evidence-base-for-treatment-decision-making-for-older-adults-with-cancer-a-workshop
- **Monday, January 25, 2021: 1:00 pm – 4:30 pm ET**
  - https://www.nationalacademies.org/event/01-25-2021/improving-the-evidence-base-for-treatment-decision-making-for-older-adults-with-cancer-a-workshop-part-2
- **Wednesday, January 27, 2021: 10:00 am – 1:30 pm ET**
  - https://www.nationalacademies.org/event/01-27-2021/improving-the-evidence-base-for-treatment-decision-making-for-older-adults-with-cancer-a-workshop-part-3

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

January 22, 2021

Dear Colleagues,

We welcome you to the National Academies virtual workshop, *Improving the Evidence Base for Treatment Decision Making for Older Adults with Cancer*. This workshop is sponsored by the Food and Drug Administration, and convened by three Forums of the National Academies: the National Cancer Policy Forum; the Forum on Aging, Disability, and Independence; and the Forum on Drug Discovery, Development, and Translation.

The workshop is planned across three dates: January 22, 2021 (1:00 pm - 4:30 pm ET), January 25, 2021 (1:00 pm – 4:30 pm ET), and January 27, 2021 (10:00 am – 1:30 pm ET). The intent of the workshop is to examine the challenges and opportunities to improve the evidence base for treating older adults with cancer. Presentations and panel discussions will examine the root causes that limit enrollment of older adults in cancer clinical trials and strategies for improved inclusion of older adults in cancer research across the drug development continuum.

We welcome your active involvement in the workshop. Please join us on the live webcast and use the chatbox to ask questions and contribute to the discussion. Please make sure you include your name and affiliation with your comments. The proceedings of the workshop in brief 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 project website.

Sincerely,

Monica M. Bertagnolli, MD, FACS, FASCO
Planning Committee Chair
Richard E. Wilson, MD Professor in the Field of Surgical Oncology
Brigham and Women's Hospital and Harvard Medical School
Group Chair, Alliance for Clinical Trials in Oncology

NATIONAL CANCER POLICY FORUM

Webcast Notes for Attendees

Improving the Evidence Base for Treatment Making Decisions for Older Adults with Cancer: A Virtual Workshop

Dates

Friday, January 22, 2021: 1:00 pm – 4:30 pm ET
Monday, January 25, 2021: 1:00 pm – 4:30 pm ET
Wednesday, 27, 2021: 10:00 am – 1:30 pm ET

Joining the Workshop

The three livestreams of the webcasts will be available for each separate workshop day here:

- **January 22 webcast:** https://www.nationalacademies.org/event/01-22-2021/improving-the-evidence-base-for-treatment-decision-making-for-older-adults-with-cancer-a-workshop
- **January 25 webcast:** https://www.nationalacademies.org/event/01-25-2021/improving-the-evidence-base-for-treatment-decision-making-for-older-adults-with-cancer-a-workshop-part-2
- **January 27 webcast:** https://www.nationalacademies.org/event/01-27-2021/improving-the-evidence-base-for-treatment-decision-making-for-older-adults-with-cancer-a-workshop-part-3

- 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 the hashtags **#NatlCancerForum, #AgingDisabilityForum, and #drugforum** 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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Improving the Evidence Base for Treatment Decision-Making for Older Adults with Cancer: A Virtual Workshop

Workshop Agenda

Part 1: Friday, January 22, 2021 Eastern Time Zone https://www.nationalacademies.org/event/01-22-2021/improving-the-evidence-base-for-treatment-decision-making-for-older-adults-with-cancer-a-workshop	
1:00 pm	**Welcome and Workshop Overview** Monica Bertagnolli, Brigham and Women's Hospital and Dana-Farber Cancer Institute Workshop Planning Committee Chair Harpreet Singh, Food and Drug Administration Workshop Sponsor Representative
1:20 pm	**Session 1: Identifying barriers and proposing solutions to increasing the evidence base for treating older adults with cancer (75 minutes)** *Co-Moderators:* *Harpreet Singh, Food and Drug Administration* *Heidi Klepin, Wake Forest School of Medicine* **Efforts to Improve the Evidence Base for Treating Older Adults with Cancer (15 minutes**) Laura Levit, American Society of Clinical Oncology Heidi Klepin, Wake Forest School of Medicine **Panel Discussion (60 minutes):** *Speakers and:* • Mary Whitehead, Cancer and Aging Research Group • Hyman Muss, University of North Carolina, Chapel Hill • Supriya Gupta Mohile, University of Rochester Medical Center • Mishu Popa-McKiver, Bristol Myers Squibb • Mina Sedrak, City of Hope
2:35 pm	**Break**
2:50 pm	**Session 2: Study designs to benefit older adults: Approaches to early phase therapeutic development (90 minutes)** *Co-Moderators:* *Donald Harvey, Emory University*

	Ishwaria Subbiah, University of Texas MD Anderson Cancer Center **Speakers (10 minutes each):** • Regulatory perspective: o Nam Atiqur (Atik) Rahman, Food and Drug Administration • Clinical perspective: o Martine Extermann, Moffitt Cancer Center • Statistical perspective: o J. Jack Lee, University of Texas MD Anderson Cancer Center • Patient advocate perspective: o Mary Lou Smith, Research Advocacy Network • Industry perspective: The Older Patient in Cancer Clinical Trials o Lilli Petruzzelli, InCyte • Pharmacology perspective: Study Designs/Approaches to Early Phase Therapeutic Development o Michael Maitland, Inova Health System **Panel Discussion (30 minutes)**
4:20 pm	**Wrap up (10 min)** Monica Bertagnolli, Brigham and Women's Hospital and Dana-Farber Cancer Institute
4:30 pm	**Adjourn Day 1**

Part 2: Monday, January 25, 2021 Eastern Time Zone https://www.nationalacademies.org/event/01-25-2021/improving-the-evidence-base-for-treatment-decision-making-for-older-adults-with-cancer-a-workshop-part-2	
1:00 pm	**Welcome from the National Academies and plans for this session (5 min)** Monica Bertagnolli, Brigham and Women's Hospital and Dana-Farber Cancer Institute
1:05 pm	**Session 3: Study designs and policy opportunities to benefit older adults: Approaches to clinical trials designed for registrational intent (85 minutes)** *Co-Moderators:* *Eric Rubin, Merck Research Laboratories* *Monica Bertagnolli, Brigham and Women's Hospital and Dana-Farber Cancer Institute*

	PART 1: STUDY DESIGNS **Overview of the 2020 FDA Draft Guidance for Industry, Inclusion of Older Adults in Cancer Clinical Trials (15 minutes)** • Harpreet Singh, Food and Drug Administration • Rajeshwari Sridhara, Food and Drug Administration **Examples of study designs/drug development strategies that could help improve the evidence base for older adults** • EA2186: A Randomized Phase II Study of Gemcitabine and Nab-Paclitaxel Compared with 5 Fluorouracil and Liposomal Irinotecan in Older Patients with Treatment Naïve Metastatic Pancreatic Cancer (GIANT) (10 minutes) o Efrat Dotan, Fox Chase Cancer Center • Inclusion of Older Adults in the Tesetaxel Development Program (10 minutes) o Kevin Tang, Odonate Therapeutics • Acute Myeloid Leukemia Trials in Older Adults (10 minutes) o Richard M. Stone, Dana Farber Cancer Institute • Capmatinib in *MET*ex14 NSCLC (10 minutes) o Monica Giovannini, Novartis • Trial Design in Older Adults: European Perspective (10 minutes) o Hans Wildiers, University Hospitals Leuven, Belgium **Panel discussion (20 minutes)**
2:30 pm	**Break**
2:45 pm	**Session 3: Study designs and policy opportunities to benefit older adults: Approaches to clinical trials designed for registrational intent (90 minutes)** **PART 2: POLICY OPPORTUNITIES** **Policy opportunities to improve the evidence base** How Ethical Principles Apply to this Workshop (10 minutes) • Rebecca Pentz, Emory University ASCO Policy Perspective (10 minutes) • Richard L. Schilsky, American Society of Clinical Oncology

	Incentives for Drug Development: Learning from the Experience of Pediatric Drug Development (10 minutes) • Aaron Kesselheim, Harvard Medical School Patient Advocacy Perspective on Policy Opportunities (10 minutes) • Sue Peschin, Alliance for Aging Research Policy Change to Improve Evidence Development for Older Adults with Cancer: If not us, who? If not now, when? • Stuart Lichtman, Memorial Sloan Kettering Cancer Center **Panel Discussion** (40 minutes)
4:15 pm	**Wrap up (15 min)**
4:30 pm	**Adjourn Day 2**

Part 3: Wednesday, January 27, 2021 Eastern Time Zone https://www.nationalacademies.org/event/01-27-2021/improving-the-evidence-base-for-treatment-decision-making-for-older-adults-with-cancer-a-workshop-part-3	
10:00 am	**Welcome from the National Academies and plans for this session (5 minutes)**
10:05 am	**Session 4: Study designs to benefit older adults: Postmarketing strategies and approaches (90 minutes)** *Co-Moderators:* *Randall Oyer, Penn Medicine Lancaster General* *Richard Schilsky, American Society of Clinical Oncology* **Speakers:** • Regulatory perspective (10 minutes) o Bindu Kanapuru, Food and Drug Administration • Study Designs to Benefit Older Adults Using Archived Clinical Trial Data (10 minutes) o Dawn Hershman, Columbia University • Real World Data (10 minutes) o Robert Miller, American Society of Clinical Oncology • **Administrative claims data (20 minutes)** o Using SEER-Medicare to Understand Patterns and Outcomes of Care for Elderly Patients with Cancer ▪ Deborah Schrag, Dana-Farber Cancer Institute

	○ Health Plan Administrative Data in Study Designs to Benefit Older Adults ▪ Jen Malin, UnitedHealthcare **Panel Discussion (40 minutes)** *Include speakers and:* • Lisa Hess, Eli Lilly and Co. • Neal Meropol, Flatiron Health
11:35 am	**Break**
11:50 am	**Session 5: Panel discussion: Participant recommendations for the path forward (85 minutes)** *Co-moderators:* *Larissa Nekhlyudov, Brigham and Women's Hospital and Harvard Medical School* *Gwen Darien, National Patient Advocate Foundation* Convene moderators for panel discussion: • **Session 1 moderators** ○ Harpreet Singh, Food and Drug Administration ○ Heidi Klepin, Wake Forest School of Medicine • **Session 2 moderators** ○ Donald Harvey, Emory University School of Medicine ○ Ishwaria Subbiah, MD Anderson Cancer Center • **Session 3 moderators** ○ Eric Rubin, Merck Research Laboratories ○ Monica Bertagnolli, Brigham and Women's Hospital and Harvard Medical School • **Session 4 moderators** ○ Richard L. Schilsky, American Society of Clinical Oncology ○ Randall Oyer, Penn Medicine Lancaster General
1:15 pm	**Wrap up and Action Plan 3 (15 min)** Monica Bertagnolli, Brigham and Women's Hospital and Dana-Farber Cancer Institute Harpreet Singh, Food and Drug Administration
1:30 pm	**Adjourn**

WORKSHOP SPONSOR:

Food and Drug Administration

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Program Leader, Senior Adult Oncology Program
Moffitt Cancer Center
Professor of Oncology and Medicine
University of South Florida
Past President
International Society of Geriatric Oncology

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Vice President
Clinical Development Head, Oncology
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Director, Breast Oncology
Co-Leader, Cancer Population Science Program
Herbert Irving Comprehensive Cancer Center
Columbia University

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Senior Research Advisor
Eli Lilly and Company

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Mary I. Whitehead, BFA
Calligrapher/Designer/Researcher
SCOREboard Patient Advocate

Hans Wildiers, MD
Medical Oncologist
University Hospitals Leuven, Belgium

SPEAKERS, PANELISTS, AND PLANNING COMMITTEE MEMBERS BIOSKETCHES

Monica M. Bertagnolli, MD, FACS, FASCO
Harvard Medical School
Brigham and Women's Hospital

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.

Gwen Darien, BA
National Patient Advocate Foundation

Gwen Darien is a longtime patient advocate who has played leadership roles in some of the country's preeminent nonprofit organizations. As executive vice president for patient advocacy and engagement, Gwen leads programs that link PAF's patient service programs to NPAF initiatives, with the goal of improving access to affordable, equitable quality health care.

Called "a bit of a renegade" by People magazine, Gwen has long insisted on pushing boundaries while maintaining a safe space for patients. As editor and publisher of Mamm, a magazine for women with breast or reproductive cancer, Gwen published features on previously taboo subjects, such as dating after a mastectomy, along with the more expected academic features on news and policy analysis. Her media leadership was recognized by the Avon Foundation, which honored her as one of "the most powerful women in breast cancer."

As a three-time cancer survivor herself, Gwen came into cancer advocacy expressly to change the experiences and outcomes for the patients who came after her and to change the public dialogue about cancer and other life-threatening illnesses. With these goals in mind, in 2005 she started the first stand-alone advocacy entity in a professional cancer research organization at the American Association for Cancer Research, causing outside observers to note the organization's "progressive commitment to patient advocacy." At AACR, she launched CR magazine – a magazine for people with cancer and those who care for them. Later, she served as the executive director of the Samuel Waxman Cancer Research Foundation; director of The Pathways Project; and executive vice president of programs and services at

the Cancer Support Community. In each role, Gwen championed placing patients at the center of health system change, whether it is for research, public policy or direct services.
While serving as the chair or on the board of a wide range of program committees and workshop faculties, including the Community Engagement in Genomics Working Group of the National Human Genome Research Institute and as the co-chair of PCORI's Patient Engagement Advisory Panel, Gwen also writes about her experiences, her most recent piece, Transformation: My Experience as a Patient and an Advocate in Three Chapters appeared in the National Academy of Medicine Perspectives.
Gwen is a graduate of Sarah Lawrence College, where she also served as an advisor for their Health Advocacy program. She grew up in Milwaukee, but now lives in New York City, where she cooks Persian dishes, collects earrings and improves her friends' personal libraries, one book at a time.

Efrat Dotan, MD
Fox Chase Cancer Center

Efrat Dotan, MD, is an Associate Professor of Medical Oncology and the Director of the Hematology/Oncology Fellowship Training Program at Fox Chase Cancer Center. Dr. Dotan received her medical degree from Technion, Israel Institute of Technology and completed her residency in internal medicine at Lenox Hill Hospital in New York City and her fellowship at Fox Chase Cancer Center in Philadelphia. She is board certified in internal medicine, hematology and medical oncology.

Dr. Dotan specializes in the management of patients with gastrointestinal malignancies with a focus on the care of older patients with GI cancers. Her research focuses on clinical trials investigating new treatment approaches for GI malignancies specifically pancreatic cancer, the development of tools to improve the assessment and care of older adults with cancer, as well as investigating novel treatment approaches for this patient population.

Dr. Dotan is the chair of the NCCN Older Adult Oncology Panel and a member the NCCN Pancreatic Cancer Guideline Panel. She is an active member of the Eastern Cooperative Oncology Group (ECOG) Gastrointestinal Malignancies Group serving as the PI for a national elderly specific pancreatic cancer study. She also serves as a senior member of the Cancer and Aging Research Group and is the founder and chair of the ECOG Geriatric Oncology Working Group.

Dr. Dotan is heavily involved in education serving as the Hematology/Oncology Fellowship Program Director at Fox Chase Cancer Center for many years. She has authors many manuscripts, review articles and book chapters and serves on the editorial board of the Journal of Geriatric Oncology and as an ad-hoc reviewer for many additional journals.

Martine Extermann, MD, PhD
University of South Florida

Dr. Martine Extermann is Professor of Oncology and Medicine at the University of South Florida. She is Program Leader in the Senior Adult Oncology Program at Moffitt Cancer Center. She earned her medical diploma and her medical PhD at the University of Geneva, Switzerland. She has a Swiss Board Certification in Internal Medicine, specialty Oncology-Hematology. She also holds ABIM certifications in Internal Medicine and Medical Oncology. She has worked at Moffitt since 1994 and has been a faculty member since 1997. Her clinical activity and research focus on cancer in older patients. Her main areas of investigation are how cancer behavior and its treatment are influenced by the general health of the patient and other diseases they have, how to predict and optimize treatment tolerance, and how to include the benefits of a comprehensive geriatric assessment (CGA) for cancer patients. Dr Extermann's research has received numerous grants from the National Institutes of Health and foundations such as

e.g. the American Cancer Society and the Kay Yow Cancer Fund/V Foundation. She has served as President of the International Society of Geriatric Oncology (SIOG), and is also a founding board member. She is the chair of the SIOG CGA task force. She serves on several American Society of Clinical Oncology (ASCO) Committees and the Editorial Board of scientific journals. Dr. Extermann has been presented with the following awards: The B.J. Kennedy Award for Scientific Excellence in Geriatric Oncology from ASCO in 2009; The Paul Calabresi Award from SIOG in 2014; A Lifetime Achievement Award in Geriatric Oncology by the German Society of Geriatrics and German Society of Hematology/Oncology in 2015.

Monica Giovannini, MD
Novartis

Monica Giovannini, MD, is a board certified medical oncologist with post degree master in clinical senology and breast cancer management. She gained her scientific and clinical background through 11 years of clinical practice and preclinical research experience in Italy (Verona University Hospital, Milan San Raffaele Scientific Institute and European Institute of Oncology) and UK (Breakthrough Breast Cancer Research Center and Royal Marsden Hospital in London) with main focus on solid tumors, especially on lung and breast disease areas with extensive experience from FIH through phase 3 studies. Since 2012 she joined Novartis taking over increasing levels of responsibility from early to late development and she is now the Clinical Development Head for Oncology.

R. Donald Harvey, PharmD, BCOP, FCCP, FHOPA
Emory University

R. Donald Harvey, PharmD, is Professor in the Emory University School of Medicine and serves as Medical Director of the Clinical Trials Office and of the Phase I Clinical Trials section at the Winship Cancer Institute. He obtained his BS and PharmD degrees at the University of North Carolina (UNC) and completed pharmacy practice and hematology oncology residencies at the University of Kentucky and UNC, respectively. His research in anticancer early drug development focuses on the application of clinical pharmacology principles to improved patient care, and he has been principal or co-investigator on over 60 phase I and clinical pharmacology trials since joining Emory in 2009 and has over 150 peer reviewed publications. Dr. Harvey is also active in clinical pharmacology and hematology/oncology professional organizations including ASCO, ASCPT, and ASH and is past Chair of the ASCO Cancer Research Committee and a Past President of the Hematology Oncology Pharmacy Association.

Dawn Hershman, MD, MS, FASCO
Columbia University Medical Center

Dr. Hershman is the Director of Breast Oncology and co-leader of the Cancer Population Science program at the Herbert Irving Comprehensive Cancer Center at Columbia University. She completed her medical degree at the Albert Einstein College of Medicine, and completed her internal medicine and oncology fellowship training at Columbia University Medical Center, where she served as Chief Resident. During that time she completed a Master's degree in Biostatistics at the Mailman School of Public Health. She has developed nationally recognized expertise in breast cancer treatment, prevention, and survivorship.

She has also developed a comprehensive multidisciplinary program to study ways of improving cancer care delivery (CCD), reducing disparities and designing studies to improve the quality of life and quality of care in BC survivors. She has received funding from the American Society of Clinical Oncology, American Cancer Society, Department of Defense, Breast Cancer Research Foundation, PCORI, and the

National Cancer Institute. She currently has several R01 grants, and has mentored numerous faculty members who have been granted mentored career development awards. Dr. Hershman has published over 250 scientific articles and has received several awards including the highly prestigious Advanced Clinical Research Award in Breast Cancer from the American Society of Clinical Oncology and the Advanced Medical Achievement Award from the Avon Foundation.

She has several national leadership roles in oncology. Within SWOG she is the Co-Pi of the NCORP Research Base and is Co-Chair of the Cancer Care Delivery Committee. Within ASCO she was selected to participate in the first Leadership Development Program and has been the Chair of the Grants Selection Committee, the leader of the education tack for Health Services, she has been on numerous committees including the quality of care committee, the obesity task force and the workforce advisory committee. She is on the editorial board for the Journal of Clinical Oncology and is an Associate Editor at the Journal of the National Cancer Institute.

Lisa Hess, PhD
Eli Lily and Company

Dr. Hess joined Eli Lilly and Company in 2012, where she currently holds a role as Senior Research Advisor, after >20 years in academia. Her academic career includes work as a scientist on multiple P01/R01 grants, the director of R25/T32 cancer prevention training grants, and as the Science Officer of the University of Arizona Cancer Center. She subsequently relocated to the Midwest and served as faculty at Indiana University Simon Cancer Center, Fairbanks School of Public Health and School of Medicine. Her education is based on the field of health outcomes (MS and PhD in Pharmaceutical Economics, Policy and Outcomes) that has supported a career focused on improving the quality of life and long-term outcomes not only among individuals who have been diagnosed with cancer, but also among those at risk of these diseases.

Bindu Kanapuru, MD
Food and Drug Administration

Dr. Kanapuru is the Clinical Team Lead for the Multiple Myeloma team in the Division of Hematologic Malignancies 2 (DHM2) in the Office of Oncologic Diseases (OOD) at the FDA. Her areas of interest include: the treatment of hematological malignancies, geriatric oncology and novel trial designs. She also serves as the scientific liaison for geriatric oncology.

Dr. Kanapuru joined the FDA in 2015. She is a board-certified hematologist-oncologist. Dr. Kanapuru completed her fellowship in hematology and oncology at the University of Maryland Medical Center in Baltimore. During her fellowship she did her research at the National Institute on Aging on mechanisms of unexplained anemia and cancer incidence in older adults, and co-authored multiple publications and book chapters. She is board-certified in Hematology and Medical Oncology.

Aaron S. Kesselheim, MD, JD, MPH
Brigham and Women's Hospital
Harvard Medical School

Aaron S. Kesselheim MD, JD, MPH, is a Professor of Medicine at Harvard Medical School and a faculty member in the Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women's Hospital. Within the Division, Aaron created and leads the Program On Regulation, Therapeutics, And Law (PORTAL, www.PORTALresearch.org), an interdisciplinary research center focusing on intersections among prescription drugs and medical devices, patient health

outcomes, and regulatory practices and the law. PORTAL is now among the largest, independent academic centers focusing on these issues in the country. Author of over 450 publications in the peer-reviewed medical and health policy literatures, Aaron has testified before Congress on pharmaceutical policy, medical device regulation, generic drugs, and modernizing clinical trials, is a member of the FDA Peripheral and Central Nervous System Advisory Committee, and served on a National Academies of Science, Engineering and Medicine consensus committees on addressing the opioid epidemic and bioidentical hormone replacement. Aaron also serves as the Sidley Austin-Robert D. McLean Visiting Professor of Law at Yale Law School, where he teaches a yearly course on Food and Drug Administration Law and Policy. He recently developed a massive open online course called *Prescription Drug Regulation, Cost, and Access: Current Controversies in Context* disseminated via the HarvardX platform to over 80,000 participants world-wide (and still available for viewing here: https://www.edx.org/course/the-fda-and-prescription-drugs-current-controversies-in-context). He is the editor-in-chief of the *Journal of Law, Medicine, and Ethics* and is a member of the Perspectives advisory board for the *New England Journal of Medicine.* In 2020, he was elected to the National Academy of Medicine.

Dr. Samir N. Khleif, MD
Georgetown University Medical Center

Dr. Samir Khleif is an immunologist and immune therapist. His research program is "translational tumor immunology" focused on understanding mechanisms through which the immune system and cancer cells interact and how to overcome tumor tolerance in developing therapeutic approaches. Specifically, his research interests include developing novel immune therapeutics, cancer vaccines and delineating the mechanisms of resistance to immunotherapy. Prior to transferring his research program to Georgetown University in 2017, Dr. Khelif served as the Director of Georgia Cancer Center, Augusta University. As Director of the Georgia Cancer Center, Dr. Khleif oversaw the development of a large integrated program of basic scientists and clinicians merging the Cancer Center strength in immunology, inflammation and tolerance basic science and immune therapy. Dr. Khleif was an intramural NIH scientist for about 20 years. While at NCI, he also served as a leader of the Cancer Vaccine Section, leading a nationally active Immune Therapy Program. His laboratory has conducted some of the earliest clinical trials in antigen vaccines and was the first to conduct vaccines against mutant oncogenes. Also, in the past few years some of the discoveries made in his laboratory have been trasnlated into first-in-human immune therapy clinical trials. Furthermore, Dr. Khleif has published several studies on the mechanisms of tumor-induced suppression in animal models and have overcome such inhibition by developing strategies that have been translated into clinical trials. His laboratory has developed models to understand how different kinds of immune therapies can be combined to work synergistically and translated into clinical trials.

Heidi D. Klepin MD, MS
Wake Forest School of Medicine

Heidi Klepin is a Professor in the Department of Internal Medicine, Section on Hematology and Oncology at the Wake Forest School of Medicine. She is a dually trained geriatrician and oncologist with a clinical and research focus on geriatric oncology. She also earned a master's degree in Health Sciences Research from Wake Forest University. Her clinical work focuses on a Geriatric Oncology Clinic, providing cancer care to adults 75 years of age or older. Her scholarly work is dedicated to improving the lives of older adults with cancer. Her research investigates the following themes among older adults with cancer: (1) patient-level characteristics as predictors of treatment outcomes; (2) the impact of chemotherapy on physical, cognitive and emotional health; and (3) interventions such as exercise to minimize treatment-associated disability and improve quality of life. She is a member of the Cancer and

Aging Research Group, member of the Alliance for Clinical Trials in Oncology Cancer in the Older Adult and Health Outcomes Subcommittees, past chair of the American Society of Clinical Oncology Cancer Research Committee and member of the American Society of Hematology Scientific Affairs Committee.

J. Jack Lee, PhD, DDS, MS
The University of Texas MD Anderson Cancer Center

J. Jack Lee is Professor of Biostatistics, Kenedy Foundation Chair in Cancer Research, and Associate Vice President in Quantitative Sciences at the University of Texas MD Anderson Cancer Center. His areas of statistical research include design and analysis of clinical trials, Bayesian adaptive designs, statistical computation/graphics, and biomarkers identification and validation. Dr. Lee has also been actively participating in basic, translational, and clinical cancer research and precision oncology. He is an elected Fellow of American Statistical Association, Society for Clinical Trials, and American Association for the Advancement of Science. He is a Statistical Editor of *Cancer Prevention Research* and serve on the Statistical Editorial Board of *Journal of the National Cancer Institute*.

Laura Levit, JD
ASCO

Laura Levit is Director of Research Analysis and Publications in the American Society for Clinical Oncology (ASCO) Center for Research and Analytics. She is the staff lead for the Cancer Research Committee and for ASCO's State of Cancer in America journal series in JCO Oncology Practice. She has worked with multiple volunteer groups to develop ASCO research statements on topics including phase I trials, older adults' participation in research, observational research, reporting immuno-oncology clinical trials, and serious adverse events reporting. Prior to joining ASCO, she was a program officer at the Institute of Medicine (now the Health and Medicine Division of the National Academies of Science, Engineering, and Medicine) where she served as the study director for the report Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis (2013). She also staffed multiple projects with the IOM's Board on Health Care Services and the National Cancer Policy Forum. Laura graduated from the University of Virginia School Of Law and is a member of the Virginia Bar Association. She completed her undergraduate studies at the College of William and Mary.

Stuart M. Lichtman, MD, FACP, FASCO
Memorial Sloan Kettering Cancer Center

Stuart M. Lichtman, is a medical oncologist at Memorial Sloan Kettering Cancer Center on Gynecologic Medical Oncology Disease Management Team and participates in the Cancer and Aging Interprofessional Team from the Division of Geriatric Medicine. His main research interest is in the treatment and evaluation of older cancer patients. In ASCO, he has been on the Clinical Practice Committee and Scientific Program Committee and Chair the Organ Dysfunction Section of the Modernizing Clinical Trials Eligibility Project and the Scientific Education Committee. Stuart is the Associate Editor for Geriatric Oncology of the ASCO Post. He has been a guest editor for the Journal of Clinical Oncology on a special edition devoted to geriatric oncology in 2007 and 2014. He is involved in several research organizations including, the Elderly Taskforce of the Gynecologic Oncology Group (currently NRG), a former member of the Gynecologic Cancer Steering Committee of the NCI, and in the Cancer in the Elderly Committee of the Alliance for Clinical Trials in Oncology. He also serves on the editorial board of the Journal of Geriatric Oncology and as faculty member of the Vail ASCO/AACR Clinical Trial Workshop for ten years and participated in the MCCR (Methods in Clinical Cancer Research) held in

Zeist, NL. Dr. Lichtman received the ASCO BJ Kennedy Award for Scientific Excellence in Geriatric Oncology in 2014, served as President of the International Society of Geriatric Oncology (2016-2018), and was the Scientific Chair of the 2017 Annual Meeting of SIOG, which was held in Warsaw.

Michael Maitland, MD, PhD
University of Virginia
Inova Health System

Michael Maitland, MD, PhD, is a physician-scientist with clinical expertise in care of patients with advanced metastatic solid tumors. His laboratory has combined patient-oriented research, quantitative biomarker development, genetics, and computational analysis methods to lead to more scientific approaches to personalizing healthcare. He has served as the principal investigator for multiple first-in-human phase 1, and organ dysfunction studies in cancer therapeutics development.

Throughout his career he has worked in multidisciplinary, frequently multi-institutional and academic-industry partnerships. Since completing dual fellowships and board certifications in medical oncology and clinical pharmacology, he received continuous peer-reviewed funding from the NIH 2007-2021 including K23, R01, U01, and T32 grants. Currently, Dr. Maitland is a Professor of Medicine at the University of Virginia but sees patients and conducts research in the community-based Inova Health System Schar Cancer Institute (ISCI) in Northern Virginia. He co-founded the ISCI geriatric clinical oncology program in 2019.

He is a former member of the National Cancer Institute Investigational Drug Steering Committee, the Journal of Clinical Oncology Editorial Board, and of the Cancer and Aging Research Group. He currently serves as Senior Editor for Quantitative and Systems Pharmacology for the American Association for Cancer Research journal, Clinical Cancer Research.

Jennifer Malin, MD, PhD
UnitedHealthcare

Jennifer Malin, MD, PhD, is a Senior Medical Director, Oncology and Genetics, at UnitedHealthcare. In this role, she provides clinical and strategic leadership for improving the health and outcomes of cancer and genomic medicine for United Healthcare members.

After graduating from Harvard University, Dr. Malin received her medical degree and doctorate in public health from UCLA. She is board certified in internal medicine and medical oncology. A Clinical Professor of Medicine at the UCLA David Geffen School of Medicine, she is the author of more than 100 peer-reviewed articles and is widely recognized for her research on the quality of cancer care. She has served on a number of advisory boards and national committees, including the American Society of Clinical Oncology's Quality of Care Committee and the National Quality Forum's Cancer Steering Committee. Prior to joining UnitedHealthcare, she was the architect of the cancer care quality program at Anthem.

Dr. Malin continues her clinical practice by volunteering at the Veterans Affairs Greater Los Angeles Health Care System. She lives in Santa Monica, California with her two children and three dogs.

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.

Robert S. Miller, MD, FACP, FASCO, FAMIA
American Society of Clinical Oncology

Robert S. Miller, MD, FACP, FASCO, FAMIA is a medical oncologist and informaticist who serves as Medical Director, CancerLinQ®, a health technology platform for oncology developed by the American Society of Clinical Oncology (ASCO). He provides scientific and clinical leadership for all aspects of CancerLinQ's strategic plan and operations. He serves as primary staff support for the CancerLinQ physician committees, and he represents ASCO and CancerLinQ in numerous external collaborations to promote cancer data sharing, interoperability, and standards, including the Minimal Common Oncology Data Elements (mCODE®) initiative. Previously, he was ASCO Vice President for Quality and Guidelines, responsible for clinical practice guidelines, performance measurement, the Quality Oncology Practice Initiative, and quality informatics. From 2009 to 2014, he served as Oncology Medical Information Officer at the Kimmel Comprehensive Cancer Center at Johns Hopkins and specialized in the care of patients with breast cancer. His additional professional experience included the community practice of oncology in California, where he was president of the Sacramento Center for Hematology and Medical Oncology, and hospice medical director.

He is a graduate of the Medical College of Virginia, now Virginia Commonwealth University. He served a residency in internal medicine at the University of California, San Francisco, and a fellowship in medical oncology at Stanford University. He also received a graduate certificate in biomedical informatics at Oregon Health and Science University. He is board certified in internal medicine, medical oncology, and

Supriya Gupta Mohile, MD, MS
University of Rochester Medical Center

Supriya Mohile, M.D., M.S. is a board-certified geriatrician and oncologist. Dr. Mohile has developed a clinical and research program in geriatric oncology by strengthening the links between geriatrics and oncology. She completed internship, residency and fellowships in hematology/oncology and geriatrics at University of Chicago Medical Center, where she also earned a Master's degree in health outcomes research. Mohile's fellowship was funded by an *American Society of Clinical Oncology (ASCO)* and John Hartford Foundation initiative to train oncologists in the care of the elderly. Since 2007, she has been funded by the NIH and others to evaluate patterns of care, health outcomes, and quality of life related to treatment for systemic cancer in older patients. In 2013, she was awarded a Patient Centered Outcomes Research Institute Award and a NCI R01 to evaluate whether geriatric assessment can improve outcomes of older patients with cancer. She founded the Specialized Oncology Care & Research in the Elderly (SOCARE) geriatric oncology clinic at the University of Rochester/Highland Hospital and is an integral member of the University of Rochester NCI Community Oncology Research Program (NCORP) Research Base. She leads the Cancer Care Delivery Research (CCDR) efforts in the Research Base. Dr. Mohile is an expert in geriatric oncology with over 180 publications in this area. She is the Editor-in-Chief of the Journal of Geriatric Oncology and co-lead for the Cancer and Aging Research Group. She chaired the *ASCO* Geriatric Oncology Clinical Guideline panel and was awarded *ASCO's* BJ Kennedy Award in 2018. Further, she is currently funded on a NIA K24 to foster the careers of rising stars in geriatric oncology.

Hyman B. Muss, MD, FASCO
The University of North Carolina, Chapel Hill

Hyman B. Muss MD is an experienced clinician-scientist, the Mary Jones Hudson Distinguished Professor of Geriatric Oncology at the University of North Carolina School of Medicine, and the Director of the Geriatric Oncology Program at the UNC Lineberger Comprehensive Cancer Center Program. He has devoted his career to breast cancer research with major interests in treatment of both early and late stages, treatment outcomes, and optimizing care for older women with breast cancer. He also has a major interest in biomarkers of aging and how they might serve as surrogate markers for help in predicting outcomes including toxicity and survival. He has served on numerous committees and boards and has played leadership roles in the American Board of internal medicine and the Alliance. He serves as the mentor for medical students, medicine residents, junior faculty, and Medical Oncology and Geriatric Oncology fellows. He recently with Dr. Jan Busby-Whitehead was awarded a T32 grant to train oncology residents in Geriatric oncology. He is committed to working with residents and students interested in projects related to Geriatric Oncology and will continue to participate in T35, T32 and other training programs focused in this area.

Larissa Nekhlyudov, MD, MPH
Brigham and Women's Hospital
Harvard Medical School
Dana-Farber Cancer Institute

Dr. Larissa Nekhlyudov is Professor of Medicine at Harvard Medical School and is a practicing primary care physician at the Brigham & Women's Hospital in Boston, Massachusetts. She is also Clinical Director, Internal Medicine for Cancer Survivors at the Dana-Farber Cancer Institute where she offers clinical care for long term survivors of childhood and adult cancers. Dr. Nekhlyudov is particularly interested in improving the care of cancer survivors and the interplay between primary and oncology care. Her publications (including journal articles, book chapters and two books) as well as her broad-ranging educational programs have promoted global awareness among health care providers about the ongoing needs of cancer patients across the care continuum. Dr. Nekhlyudov has been at the forefront

of the field of cancer survivorship, nationally and internationally, by leading and participating in the development of policies, clinical guidelines, educational programs and research.

Dr. Nekhlyudov is an active member of the American Society of Clinical Oncology, the National Comprehensive Cancer Network, and the Society of General Internal Medicine, and is an Executive Member of the Cancer and Primary Care Research International Network (Ca-PRI). She has previously served on several National Academies of Sciences, Engineering and Medicine (NASEM) activities including the Committee on the Quality of Cancer Care: Addressing the Challenges of an Aging *Population* and Planning Committee for *Long-Term Survivorship Care after Cancer Treatment: A Workshop*. Dr. Nekhlyudov currently serves on the NASEM *Committee on Diagnosing and Treating Adult Cancers*. During her recent 18 month tenure as the Inaugural National Cancer Institute (NCI)-AcademyHealth Visiting Scholar, she developed a framework for quality survivorship care that has now been adapted by the NCI Office of Cancer Survivorship and has led to numerous national and international initiatives. Throughout her career, Dr. Nekhlyudov has been dedicated to teaching and mentoring students, residents, fellows and faculty. She has also been committed to empowering cancer survivors and caregivers through educational programs.

Dr. Nekhlyudov received her M.D. from the Mount Sinai School of Medicine and completed residency training at Yale-New Haven Hospital/Yale Primary Care Residency Program. She completed the Harvard Medical School Fellowship in General Medicine and Primary Care and received a Masters of Public Health degree from the Harvard School of Public Health. Dr. Nekhlyudov has been on faculty at Harvard Medical School since 1999.

Randall A. Oyer, MD
Penn Medicine Lancaster General

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.

Rebecca D. Pentz, PhD
Emory University School of Medicine

Rebecca D. Pentz, PhD, Professor of Research Ethics, Winship Cancer Institute, Emory University School of Medicine has had the unique opportunity for an ethicist with a PhD in philosophy to have been embedded in all aspect of cancer care for the last 30 years. Dr. Pentz reconstituted and directed the Clinical Ethics service at The University of Texas M.D. Anderson Cancer Center for a decade, handling ethical dilemmas arising from the first day a patient stepped in the door to futility at the end of life. Dr. Pentz now directs the Research Ethics program at Winship, providing research ethics consults and conducting empirical ethics research, with a focus on disparities. She created, tested and is now disseminating educational short videos to explain terms used to describe chemotherapy treatments and

the new precision medicines. She has successfully tested these videos in the underserved urban population in Atlanta and in Georgia's rural population. The ethics program is now developing programs for rural and older patients and the Latinx community. She is aware of past age discrimination against children in clinical trials, having been the sole patient advocate/ethicist for the Children's Cancer Group in the early 1990s, and now serving on the Children's Oncology Group's ethics, minority affairs, and patient advocacy committees. With this experience, Dr. Pentz is prepared to provide the ethical perspective on the issues facing attempts to improve the evidence base for treatment decision-making for older adults with cancer.

Susan Peschin, MHS
Alliance for Aging Research

Susan Peschin, MHS, is president and CEO at the Alliance for Aging Research, the leading national non-profit organization dedicated to accelerating the pace of scientific discoveries and their application to improve the experience of aging and health. Since 2012, Ms. Peschin has been a driving force in the growth and success of the organization. As a thought leader on many aging-related issues, she has led the Alliance in efforts to: boost older adult immunization rates; increase NIH Alzheimer's disease and aging research funding; raise awareness of geriatric cardiac issues; develop Talk NERDY to Me (NERDY-Nurturing Engagement in Research and Development with You), a PCORI-funded, older patient and family caregiver research engagement network; address costs of healthcare and value frameworks; and reform Medicare treatment access issues. She participates in major industry and policy symposiums around the country each year and has published opinion pieces in news outlets nationwide. Ms. Peschin currently serves on the Boards of Heart Valve Voice U.S. and the King Farm Neighbors Village; and on the National Advisory Council for the National Institute on Aging at the NIH.

Ms. Peschin earned a B.A. in Sociology from Brandeis University, and a M.H.S. degree in Health Policy from the Johns Hopkins University Bloomberg School of Public Health.

Lilli Petruzzelli, MD, PhD
Incyte

Lilli received a bachelor of science in chemistry and biology from MIT and her MD and PhD from Albert Einstein College of Medicine. She did her internship and residency training in Internal Medicine and her fellowship in Hematology at the Brigham and Women's Hospital and Harvard Medical School in Boston. From 1994 until 2007, she was a faculty member and associate professor in the department of Hematology and Oncology at the University of Michigan where she established a laboratory-based research program focused on the regulation of integrin-dependent adhesion in leukocytes and a clinical practice specializing in hematologic malignancies.

Lilli began her career in the pharmaceutical industry at Millennium in 2007, where she played a key role in the development of the Nedd-8 activating enzyme inhibitor and the oral second-generation proteasome inhibitor, Ninlaro. She joined Novartis in 2009 as a physician focusing on translational medicine in oncology and had increasing roles of responsibility most recently leading Translational Clinical Oncology group since 2014. There she oversaw the development of the early oncology pipeline including the registration study for the ALK inhibitor Zykadia, the early development of Kisqali, the development a novel BCR-ABL inhibitor, ABL001, and the entire pre-PoC target and immune-oncology portfolios. In November of 2019, she joined Incyte to lead their early clinical development programs.

Mishu Popa-McKiver, MD, PhD

Bristol Myers Squibb Company

Mishu Popa-McKiver, currently Clinical Development Lead, Hematology Global Drug Development at Bristol Myers Squibb, completed her medical and fellowship training in Geriatrics in Romania. She pursued graduate education in aging in the US, and achieved a Master's in Gerontological Studies from Miami University of Ohio and a Doctorate in Aging Studies from University of South Florida. Aging and cancer came together during her post-doctoral fellowship at Moffitt Cancer Center, under the mentorship of two geriatric oncology pioneers, Drs. Martine Extermann and Lodovico Balducci. Her post-doctoral research focused on drug-drug interactions from polypharmacy in older cancer patients receiving chemotherapy. Currently, she is leading the clinical development for several multiple myeloma assets.

Barbara Radziszewska, PhD, MPH
National Institute of Aging

Barbara Radziszewska is a Health Scientist Administrator in the Clinical Trials Branch of the Division of Geriatrics and Clinical Gerontology at the National Institute on Aging, NIH. Her educational background is in developmental psychology (Ph.D., University of Utah, 1987) and in public health (MPH, Johns Hopkins University, 1995). She has worked at NIH since 1996, focusing on scientific, programmatic and regulatory aspects of clinical trials and epidemiological studies. Throughout her career at NIH, Dr. Radziszewska has provided oversight and direction to clinical trials focusing on primary and secondary prevention and treatment of age-related conditions, including cardiovascular disease and functional decline.

Nam Atiqur Rahman, PhD
Food and Drug Administration

Nam Atiqur Rahman, is the Director of the Division of Cancer Pharmacology II within the Office of Clinical Pharmacology (OCP), OTS, CDER, US Food and Drug Administration (USFDA). The Division includes clinical pharmacology reviewers who are involved in the development, review, approval, and life cycle management of the drugs and therapeutic biologics for solid tumors. Prior to joining FDA, Dr. Rahman earned his doctorate degree from the Washington State University and completed post-doctoral training at the St-Jude Children's Research Hospital, Memphis, Tennessee in Molecular Pharmacology and Pharmacogenomics.

Dr. Rahman's current interest includes immunoncology, dose optimization, and application of modeling and simulation in cancer drug development. Dr. Rahman interest also includes the application of pharmacogemonics to promote personalized medicine for cancer patients. He supports the review staff that addresses various scientific challenges in drug development and approval from Clinical Pharmacology perspectives and interacts with pharmaceuticals to promote and facilitate innovation in drug development. In addition, Dr. Rahman is working with national scientific society, American Society of Clinical Oncology and the patient advocacy group, Friends of Cancer Research (FOCR) to modernize the eligibility criteria for entry of patients in clinical trial for drug development.

Dr. Rahman received over 40 FDA level awards, published 55 articles in peer review journals and authored 6 book chapters. He has given over 50 presentations in national and international meetings, workshops and symposiums. He is currently a member of American Society of Clinical Oncology.

Eric H. Rubin, MD

Merck Research Laboratories

Dr. Rubin has focused on cancer drug development for over 25 years, initially as a faculty member at the Dana-Farber Cancer Institute, then as a senior leader of the Cancer Institute of New Jersey, where he served as the Director of the Investigational Therapeutics Division of that institution. His research efforts focused on mechanisms of resistance to DNA topoisomerase-targeting drugs and his laboratory cloned TOPORS, a novel topoisomerase I- and p53-interacting tumor suppressor gene. In 2008 he was recruited to Merck to lead the clinical oncology development team. Under his leadership, the clinical oncology group underwent a transformational change in an effort to realize the potential of cancer immunotherapy. He led the initial development of the anti-PD-1 antibody pembrolizumab, which was the first anti-PD-1 therapy approved in the U.S., and in the identification of the significant activity of this breakthrough therapeutic across several cancer types. In 2014 Dr. Rubin was asked to head up Oncology Early Development for Merck, and in this role he oversees development of a promising and expansive early pipeline, as well as translational oncology research activities.

Dr. Rubin has authored over 100 original, peer-reviewed publications and book chapters related to oncology translational research, clinical trials, and drug development. He has served frequently as a member of National Cancer Institute and American Cancer Society study sections, as well as on program committees for the American Association of Cancer Research (AACR) and the American Society of Clinical Oncology. He is a co-chair of the Cancer Steering Committee of the Biomarkers Consortium, Foundation of the National Institute of Health, a member of the Science Policy and Governmental Affairs Committee for AACR, and was a member of the National Cancer Moonshot Initiative/Blue Ribbon Panel Working Group on Expanding Clinical Trials.

Richard L. Schilsky, MD, FACP, FSCT, FASCO
American Society of Clinical Oncology

Dr. Schilsky is the Executive Vice President and Chief Medical Officer (CMO) of ASCO. Formerly the Chief of Hematology/Oncology in the Department of Medicine and Deputy Director of the University of Chicago Comprehensive Cancer Center, he is a highly respected leader in the field of clinical oncology. He specializes in new drug development and treatment of gastrointestinal cancers. Dr. Schilsky is a Past President of ASCO, having served in the role during 2008-2009, and also a Past Chair of one of the National Cancer Institute's Cooperative Groups, Cancer and Leukemia Group B (CALGB).

Dr. Schilsky's impressive experience and many accomplishments in both clinical medicine and clinical research reflect his deep passion for cancer medicine. He has spent the majority of his career at the University of Chicago where he joined the faculty in 1984, subsequently rising to the rank of Professor of Medicine and serving in many roles, including Associate Dean for Clinical Research in the Biological Sciences Division and Director of the University of Chicago Cancer Research Center.

From 1995 to 2010, Dr. Schilsky served as chair of the Cancer and Leukemia Group B, a national cooperative clinical research group funded by the National Cancer Institute (NCI). He has extensive experience working with both the NCI and the Food and Drug Administration (FDA) having served as a member and chair of the NCI Board of Scientific Advisors, as a member of the NCI Clinical and Translational Research Committee, and as a member and chair of the Oncologic Drugs Advisory Committee of the FDA. Presently, he serves as a member of the board of directors of Friends of Cancer Research and of the Reagan-Udall Foundation for the FDA. Dr. Schilsky has served on the editorial boards of many cancer journals, including the *Journal of Clinical Oncology*. He presently serves on the editorial board of the *New England Journal of Medicine*. Dr. Schilsky is the author of more than 400 original research articles, reviews and commentaries.

Early in his career, he worked in the Clinical Pharmacology Branch of the Division of Cancer Treatment at the NCI and was an Assistant Professor in the Department of Internal Medicine, Division of Hematology and Oncology at the University of Missouri-Columbia School of Medicine. He was also the head of the hematology/medical oncology unit at the Harry S. Truman Veterans' Administration Hospital in Columbia, Missouri.

Deborah Schrag, MD, MPH
Dana-Farber Cancer Institute
Harvard Medical School

Deb Schrag, is Chief of the Division of Population Sciences at Dana-Farber Cancer Institute and Professor of Medicine at Harvard Medical School in Boston, MA. She is a health services researcher and gastrointestinal medical oncologist with focus on colorectal cancer. Her research focuses on improving the quality, effectiveness and cost-effectiveness of cancer care delivery. She leads the Harvard Program in Cancer Care Delivery Research, is the PI of several multi-center trials and leads efforts to develop data standards to characterize outcomes of cancer treatment at population-scale. She has performed foundational work in patient-reported outcomes and building phenomic data standards to systematically measure outcomes from electronic health records. Dr. Schrag is an Associate Editor of the Journal of the American Medical Association, a fellow of the American Society of Clinical Oncology and a former Board of Director, a past member of the National Cancer Policy Forum and an elected member of the American Association of Physicians.

Mina Sedrak, MD, MS
City of Hope

Dr. Sedrak is an Assistant Professor in the Department of Medical Oncology and Deputy Director of Clinical Trials in the Center for Cancer and Aging at City of Hope. He is a medical oncologist who specializes in the care of older adults with breast cancer. His research is at the intersection of geriatrics, oncology, and aging biology. He leads cancer therapeutic trials designed specifically for older and/or frail adults with cancer, capturing endpoints that are pertinent to this population, such as preservation of function, cognition, and independence. His work also aims to address barriers to enrollment of older adults in cancer research. Dr. Sedrak completed his hematology/oncology fellowship at the University of Pennsylvania, where he also earned a master's degree in health policy research. His work has been supported in part by the National Institute on Aging (NIA), National Cancer Institute (NCI), and The Hope Foundation for Cancer Research.

Harpreet Singh, MD
Food and Drug Administration

Dr. Harpreet Singh is the Director of the Division of Oncology 2 in the Office of Oncology Diseases, as well the Acting Associate Director for Cancer in Older Adults and Special Populations in the Oncology Center of Excellence at the US FDA.

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

As Director of the Division of Oncology 2, Dr. Singh oversees drug development for lung cancer, head and neck cancer, neurologic tumors, pediatric solid tumors, and rare cancers. Her scope of expertise includes precision medicine and targeted therapy, novel trial design, innovative regulatory initiatives

designed to expedite drug approvals, and use of real world data in regulatory decision making. Recent notable approvals in lung cancer include targeted therapies for MET exon 14 skipping mutations and RET fusions. In her role as AD for Cancer in Older Adults, Dr. Singh leads multiple OCE efforts to advance drug development and regulatory science for older adults with cancer and special populations. Dr. Singh has expertly engaged with the greater scientific community, to increase the evidence base for treating older adults with cancer. She has consistently presented her FDA research on this topic at major academic conferences, and published in peer reviewed journals such as the Journal of Clinical Oncology (JCO). Most recently, she spearheaded an She serves as the lead for OCE's Project Silver, a global regulatory effort to increase the evidence base for older adults with cancer. Under Project Silver, global regulatory agencies will discuss key applications and development programs with indications affecting older adults with cancer, consider more detailed labeling information that reflects the clinical experience of older adults, and conduct educational programs with global stakeholders.

Dr. Singh maintains her clinical credentials at the National Cancer Institute.

Mary Lou Smith, JD, MBA, FASCO
Research Advocacy Network

Mary Lou Smith is a Co-founder of the Research Advocacy Network. She is a two-time breast cancer survivor and an ovarian and colon cancer survivor and serves as Chair of the ECOG-ACRIN Cancer Research Advocates Committee. She also serves on the National Comprehensive Cancer Network (NCCN) Breast Cancer Screening and Treatment Guidelines Committees. She is a member of the Mayo Breast SPORE and the NCI Breast Cancer Steering Committee. Mary Lou serves on the Board of Gateway for Cancer Research. She was a community member of the Rush University Medical Center Institutional Review Board for 10 years. Mary Lou is past president of Y-ME National Breast Cancer Organization and has served on the Cancer Leadership Council and the National Breast Cancer Coalition's Board of Directors.

Mary Lou has worked in health care for over 20 years in both hospital administration and consulting. She was involved in the development of numerous managed care products for the Blue Cross and Blue Shield Association, including a Pediatric Cancer Network. Mary Lou has a Juris Doctorate with a Health Law Certification and a master's degree in Business Administration.

Rajeshwari Sridhara, PhD
Food and Drug Administration

Rajeshwari Sridhara is a biostatistician working as a contractor at the Oncology Center of Excellence, Food and Drug Administration (FDA). She recently retired after 20 years at FDA as the Division Director of Division of Biometrics V, Office of Biostatistics which supports Office of Oncology Drug Products at the Center for Drug Evaluation and Research (CDER), FDA. Dr. Sridhara has contributed to the understanding and addressing the statistical issues that are unique to the oncology disease area such as evaluation and analysis of time to disease progression. Her research interests also include evaluation of surrogate markers and design of clinical trials. She has organized, chaired and given invited presentations at several workshops. She has worked on many regulatory guidance documents across multiple disciplines. She has extensively published in refereed journals and presented at national and international conferences. She is an elected Fellow of the American Statistical Association. Prior to joining FDA, Dr. Sridhara was a project statistician for the AIDS vaccine evaluation group at EMMES Corporation, and she was an Assistant Professor at the University of Maryland Cancer Center.

Richard Maury Stone, MD
Dana-Farber Cancer Institute
Harvard Medial School

Richard Stone, MD, is the Chief of Staff at Dana-Farber Cancer Institute (DFCI). He is also Director of Translational Research for the Leukemia Division in the Department of Medical Oncology at DFCI, and Professor of Medicine at Harvard Medical School. Dr. Stone is nationally recognized for his translational and clinical research concerning blood and bone marrow malignancies including acute leukemia, myeloproliferative disorders and myelodysplastic syndrome [MDS] (a bone marrow failure state that may convert to leukemia).

In addition to his work at Dana-Farber, Dr. Stone serves as Chairman of the Leukemia Committee for the national cooperative trials group, Alliance. He is a Vice Chair of the National Comprehensive Cancer Network (NCCN) MDS panel and is also a member of the NCCN AML panel. He previously served as the Chair of the Medical Advisory Board of the Aplastic Anemia and MDS International Foundation, the Chair of the ABIM Oncology Board, and has served on the editorial boards of *Leukemia Research*, *Blood* and *Journal of Clinical Oncology*.

Dr. Stone has participated extensively in teaching medical students, residents, and fellows, as well as graduate medical education courses on leukemia and related disorders. He is the author of many academic papers that have been published in the *New England Journal of Medicine*, *Blood*, *Leukemia* as well as numerous other journals. He had a significant leadership role in the development of five new drugs for the treatment of acute myeloid leukemia (AML) that were approved in the past two years. He is the Co-Principle Investigator of the SPORE in Myeloid Malignancies at Dana-Farber/Harvard Cancer Center.

Dr. Stone earned his medical degree from Harvard Medical School in 1981. He completed his internal medicine residency training and served as Chief Medical Resident at Brigham and Women's Hospital. He completed his hematology-oncology fellowship at Dana-Farber.

Ishwaria Subbiah, MD
The University of Texas MD Anderson Cancer Center

Dr. Ishwaria Subbiah is a Palliative Care physician and medical oncologist in the Division of Cancer Medicine at MD Anderson Cancer Center. Dr. Subbiah is uniquely qualified for this role, having completed 3 clinical fellowships at MD Anderson first in Developmental Therapeutics, then in Medical Oncology and most recently in Palliative Medicine. With this robust foundation in phase I and II clinical trial design, novel therapeutics including immunotherapy and targeted therapies, fundamentals of medical oncology practice, and symptom management, Dr. Subbiah cultivates a clinical practice as well as research and advocacy focus on supportive care driven by patient reported outcomes (PROs) for all patients with particular emphasis on the older adults.

Dr. Subbiah has been the principal investigator on several studies for older adults with advanced cancers on phase I clinical trials. She has published in multiple journals including the Journal of Clinical Oncology and has received several peer-reviewed grants including from the American Cancer Society and Andrew Sabin Family Foundation. In 2018 she was recognized by the National Institute on Aging (NIA) of the National Institutes of Health (NIH) as a Butler-Williams Scholar, a highly competitive program for early career investigators in all fields of aging research.

Dr. Subbiah chairs the Patient Survey Governance Committee at MD Anderson overseeing the institution-wide implementation of PROs into clinical practice. Currently, Dr. Subbiah co-leads the PRO

team that developed a novel COVID-specific PRO instrument and implemented a remote symptom monitoring platform for patients with cancer and COVID-19, a population particularly vulnerable for the negative outcomes including hospitalizations and death. This remote monitoring system from Dr. Subbiah and team is designed to identify early changes in the patient's health during their COVID-19 infection to ensure an early intervention from the medical team.

She also serves on the national Technical Expert Panel developing oncology PRO measures for the Centers for Medicare & Medicaid Services (CMS) and on the Older Adult Oncology guidelines committee of the National Comprehensive Cancer Network (NCCN). Her ardent patient-level and institutional efforts as well as national/international advocacy reflect her commitment to develop the model of oncologic care that seamlessly (and synergistically) integrates both cutting edge anti-cancer therapies and comprehensive holistic supportive care to deliver a cancer treatment experience in line with the values of each patient and their family.

Kevin Tang, BS
Odonate Therapeutics, Inc.

Mr. Tang has served as Chairman and Chief Executive Officer of Odonate Therapeutics, Inc. since its inception in 2013. He also serves as President of Tang Capital Management, LLC, a life sciences-focused investment company he founded in 2002. Since 2014, Mr. Tang has served as a director and Chairman of La Jolla Pharmaceutical Company. From 2009 to 2020, he served as a director of Heron Therapeutics, Inc. and, from 2012 to 2020, served as Chairman. From 2009 through its acquisition by Endo Pharmaceuticals, Inc. in 2010, Mr. Tang served as a director of Penwest Pharmaceuticals Co. In 2006, he co-founded Ardea Biosciences, Inc. and served as a director from inception through its acquisition by AstraZeneca PLC in 2012. From 2001 to 2008, Mr. Tang served as a director of Trimeris, Inc. From 1993 to 2001, he held various positions at Deutsche Banc Alex Brown, Inc., an investment banking firm, most recently serving as Managing Director and head of the firm's Life Sciences research group. Mr. Tang received a B.S. degree from Duke University.

Mary I. Whitehead, BFA
Patient Advocate

Mary is an independent Patient Advocate; an 18-yr survivor of breast cancer; a graduate of ProjectLEAD (sponsored by NBCC) in 2006; Peer Reviewer for the DOD 2005-2009; Patient Care Committee, Sharon Hospital, Sharon, CT. (now NUVANCE); Sub-Committee for ERA of Hope (2011); Member of SCOREboard (URMCC) as a Patient Advocate for the past 7 years, and now also a member of CARinG SCOREboard, on the CORE for Supportive Care, coordinated and chaired by URMCC and City of Hope. She has attended most of the ASCO Annual Meetings between 2010 and 2018, and was honored by ASCO as an Advocacy Champion in 2017.

She lives in Sharon, CT., and spends her time advocating for a population which is more rural than urban, and is happy to be working on issues which affect the senior population of Americans.

Hans Wildiers, MD
University Hospitals Leuven, Belgium

Hans Wildiers is a medical oncologist dedicated to breast cancer research and geriatric oncology. He is staff member at the department of medical oncology in the University Hospital Leuven, Belgium since 2004. He coordinates the Leuven multidisciplinary breast center since 2015. He has been coordinator of

several academic studies in the field of breast cancer and geriatric oncology, and author of more than 230 peer reviewed papers. He has been active within the board of SIOG, the international society of geriatric oncology, for many years, and serves this organization as president from 11-2018 till 10-2020. From 2009 till 2015, he has chaired the elderly task force cancer of the elderly of the European Organization of Research and Treatment of Cancer (EORTC).

Inclusion of Older Adults in Cancer Clinical Trials

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Harpreet Singh at 240-402-3561 or (CBER) Office of Communication, Outreach and Development at 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Oncology Center of Excellence
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

March 2020
Clinical/Medical

Inclusion of Older Adults in Cancer Clinical Trials

Guidance for Industry

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Food and Drug Administration
Oncology Center of Excellence
Center for Drug Evaluation and Research (CDER)
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Inclusion of Older Adults in Cancer Clinical Trials
Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance provides recommendations regarding the inclusion of older adult patients in clinical trials of drugs[2] for the treatment of cancer. For the purpose of this guidance, older adults are those aged 65 years and older. Specifically, this guidance includes recommendations for including an adequate representation of older adults in cancer clinical trials to better enable evaluation of the benefit-risk profile of cancer drugs in this population. The guidance emphasizes the particular importance of including adults over age 75 years in cancer clinical trials. This guidance is intended to assist stakeholders, including sponsors and institutional review boards, responsible for the development and oversight of clinical trials.

Enrolling an adequate representation of the range of patients in a clinical trial that may be exposed to a drug after approval can maximize the generalizability of the trial results. It provides the ability to understand the drug's benefit-risk profile across the patient population likely to use the drug in clinical practice (e.g., to identify whether there are differences in the benefits, risks, or both of the drug in different populations). Including information in the labeling describing use in older adults helps to promote the safe and effective use of these products and better informs treatment decisions in clinical practice.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] This guidance has been prepared by the Oncology Center of Excellence, Center for Drug Evaluation and Research (CDER), and Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration.

[2] For the purposes of this guidance, references to drugs includes drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

II. BACKGROUND

Adults aged 65 years and older, and especially those over age 75, are underrepresented in cancer clinical trials despite representing a growing segment of the population of cancer patients.[3,4] Therefore, developing more information is important to better inform treatment decisions for older adults with cancer. Cancer is a disease associated with age, with the number of cancer cases projected to multiply due to rapid aging of the U.S. population.[5] FDA is engaged with stakeholders to improve the representation of older adults in cancer trials.

The issue persists in oncology despite FDA's efforts to increase the inclusion of older adults in clinical trials. FDA has encouraged the inclusion of older adults in clinical trials, including through several guidance documents.[6] In addition, FDA published a series of draft guidances that would encourage sponsors to broaden cancer clinical trial eligibility criteria to maximize the generalizability of trial results and the ability to understand the drug's benefit-risk profile across the patient population likely to use the drug in clinical practice. One draft guidance in the series, *Cancer Clinical Trial Eligibility Criteria: Patients with Organ Dysfunction or Prior or Concurrent Malignancies*,[7] is particularly relevant to older adults. The draft guidance would encourage the inclusion of patients with organ dysfunction and with prior or concurrent malignancies, as appropriate, to better reflect the population that will use the drug in clinical practice. The draft guidance includes specific draft recommendations regarding the inclusion of patients with renal, cardiac, and hepatic dysfunction and of patients with prior or concurrent malignancy, all of which may increase with age.

Differences may exist between younger and older patients in drug response and toxicity due to age-related physiologic changes. For example, the pharmacokinetics of the drug, or the pharmacodynamic response to the drug, or both may vary between younger and older patients. In addition, older adults often have comorbidities and may be taking concomitant medications that could impact the efficacy of either the cancer drug or other drug(s) they are taking, and may also impact the incidence and the severity of adverse events. It is important that the spectrum of older adults included in clinical trials are representative of the intended population, including those with physiological decline (e.g., frailty). Furthermore, there may be important differences

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[3] Singh H, Kanapuru B, Smith C, et al., 2017, FDA Analysis of Enrollment of Older Adults in Clinical Trials for Cancer Drug Registration: A 10-Year Experience by the U.S. Food and Drug Administration, JCO, 35:15 suppl, 10009-10009.

[4] Smith BD, Smith GL, Hurria A, et al., 2009, Future of Cancer Incidence in the United States: Burdens Upon an Aging, Changing Nation, JCO, 27(17): 2758-65.

[5] Levit L, Singh H, Klepin H, Hurria A, 2018, Expanding the Evidence Base in Geriatric Oncology: Action Items from an FDA-ASCO Workshop, JNCI, 110(11): djy169.

[6] See the guidance for industry *Guideline for the Study of Drugs Likely to Be Used in the Elderly* (November 1989), guideline for industry *Studies in Support of Special Populations: Geriatrics* (ICH E7) (August 1994), guidance for industry *Content and Format for Geriatric Labeling* (October 2001), guidance for industry *E7 Studies in Support of Special Populations: Geriatrics Questions and Answers* (February 2012), and draft guidance for industry *Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs* (June 2019). When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[7] March 2019. When final, this guidance will represent the FDA's current thinking on this topic.

in efficacy in older patients compared to the younger or general population, and information describing such differences should be conveyed to patients and healthcare providers where appropriate.

Geriatric (i.e., older adult) use information must be included in labeling, unless clearly inapplicable.[8] FDA's guidance for industry *Content and Format for Geriatric Labeling* describes the content and format of geriatric use information in labeling for human prescription drug and biological products to guide their safe and effective use in geriatric patients. In addition, FDA's Drug Trials Snapshots[9] is an effort to make demographic data, including age, more available and transparent by providing consumers with information about the demographic profile of the clinical trial participants for new molecular entities and biologics approved in 2015 and later. Demographic information may also be available on FDA's website within the posted product approval information. In particular, Snapshots can highlight differences in benefits and side effects among demographic groups, including, for example, differences based on age when a clinical trial includes a representative population of older adults.

III. RECOMMENDATIONS

Clinical trials should include study populations reflecting the intended population that may receive the intervention being evaluated if approved. In general, to achieve an unbiased estimate of treatment effect in the general population, sponsors should develop a strategy to enroll diverse populations, including different age groups, that are consistent with the intended use population. For most cancers, clinical trials should include a representative population of older adults.[10] Older adults, including those with frailty, should be enrolled in all phases of clinical trials, when they can be safely and ethically enrolled.

Sponsors of cancer trials should consider the age demographics of their target population early in development. CDER and CBER are available to discuss plans for enrollment of older adults in cancer clinical trials, particularly when enrollment of adequate representation of older adults may be challenging.

A strategy regarding inclusion of older adults should be informed by any known information for older adults, including for example, prevalence of the condition, diagnosis and treatment patterns, prior relevant studies, and differences in outcomes related to safety or efficacy. The draft guidance for industry *Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs* includes draft recommendations for inclusive trial practices, trial design and methodological approaches, and other study design and conduct considerations for improving enrollment that sponsors should consider regarding older adults.

[8] See 21 CFR sections 201.56(d)(4), 201.57, and 201.80.

[9] Available at https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots

[10] One source of data that may be considered when estimating the incidence of a cancer in older adults is the National Cancer Institute's Surveillance, Epidemiology, and End Results Program, SEER Incidence database, available at https://seer.cancer.gov/data/.

To understand potential age-related differences that may be relevant to the clinical development of a cancer drug, FDA recommends the following:

A. Early Clinical Development

- Sponsors should enroll older adults, if appropriate, in early phase studies to obtain information on safety, exposure, and response to better inform the study design and dose selection of later phase studies.

- Sponsors should evaluate drug-drug interactions early in drug development to allow enrollment of older adults who may otherwise be excluded because of their concomitant medication use.

B. Clinical Trials

- *Trial design*

  Sponsors should make every effort to enroll older adults in their pivotal randomized trials. To encourage and facilitate the enrollment of older adults in cancer trials, FDA is available to discuss flexible approaches to trial design and analysis. For example, it may be acceptable to design a trial with stratification based on age, so that analyses can focus on benefits and risks among older adults. Alternatively, an open-label safety study can enroll and analyze an older adult population separately in a parallel arm of a trial. In some cases, the older adult arm(s) can be actively accruing at the time of NDA or BLA submission.

  An example of a possible trial design approach is a randomized controlled trial that enrolls younger and older adults and stratifies by age. The intent-to-treat (ITT) population consists of all enrolled patients, a modified ITT (MITT) consists only of the patients under 75 years of age. The trial would use hierarchical testing, and the primary analysis would be conducted in the MITT population, with subsequent analyses in the ITT population to provide safety and efficacy information about all patients. If the size of the older patient population is adequate and hypothesis driven, results in the older population can also be analyzed separately.

  Distinctive benefit-risk considerations should be considered during drug development for older adults. We recommend that sponsors consider perspectives of older adults, including those of patients and patient and caregiver partners, clinicians, and advocacy groups, during the design of the clinical trial protocol to ensure patient preferences are incorporated in clinical trial activities, when possible, to facilitate enrollment of older adults as well as improve identification of meaningful endpoints and overall trial design.[11]

[11] See draft guidance for industry *Patient-Focused Drug Development: Collecting Comprehensive and Representative Input* (June 2018). When final, this guidance will represent the FDA's current thinking on this topic.

- *Develop recruitment strategies targeted to older adults*

  In general, most cancer trials do not have an upper age limit for exclusion, however, older adults, particularly adults 75 years and older continue to be underrepresented in these trials. FDA encourages sponsors and clinical trial cooperative groups to develop strategies to recruit patients that are reflective of the intended population. Possible challenges with recruiting older adults that could be mitigated, particularly among patients over 75 years, include: location of clinical trial sites (e.g., sites in community-based settings may be more accessible to older adults than sites located in urban academic centers), format and content of informational material for the trial, caregiver support, accommodations needed for impairment (e.g., visual, mobility, cognitive, etc.), and travel and other logistics.

  Sponsors should discuss specific goals for enrollment of older adults with clinical investigators and keep the clinical trial sites updated on the progress of enrolling older adults in the trial. Sponsors should discuss the importance of enrolling older adults during study training provided to the clinical sites. In addition, sponsors should consider recruitment of geriatric oncologists and oncologists with expertise in treating older adults.

- *Consider collecting additional information for older adults*

  Sponsors should prospectively consider information that should be collected for older adults that will be clinically informative and will provide an understanding of clinical outcomes in older adults. For example, in addition to collection of age and performance status, elements from geriatric assessment tools, such as functional status and cognitive function, or frailty measures and a comprehensive assessment of comorbidities should be considered during trial design.[12] Incorporating a patient reported outcome instrument(s) in cancer trials may encourage older adults to participate in clinical trials and the information obtained may inform future research.[13]

- *Consider additional strategies in adverse event monitoring and management*

  Older adult patients' experience with adverse events may differ from younger patients. Developing strategies to capture and manage adverse events in older patients (e.g., supportive care measures, involvement of geriatric oncologists and health care professionals with expertise in treating older adults) may facilitate older patients completing the trial.

[12] Singh H, Beaver JA, Kim G, Pazdur R, 2016, Enrollment of Older Adults on Oncology Trials: An FDA Perspective, JGO, 8: 149-50.

[13] See the guidance for industry *Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims* (December 2009).

- *Develop and report more discrete age subgroups*

  Because outcomes of cancer patients aged 65 and older may vary by age, sponsors should identify subgroups within the population of patients aged 65 and older for analysis, as relevant, to best understand the drug's benefits and risks in older adults. For example, subgroups such as age 65 years to 74 years and 75 years and older may be relevant. A particular need exists for evidence in patients older than 75 years. Reporting clinical trial data from older adults in a more standardized and granular way can be more clinically useful.[14] FDA's guidance for industry *Integrated Summary of Effectiveness* (October 2015) includes recommendations regarding subpopulation assessment and reporting in the NDA or BLA that are applicable to subgroups of older adults in cancer trials (see section III.D of that guidance).

C. Postmarket

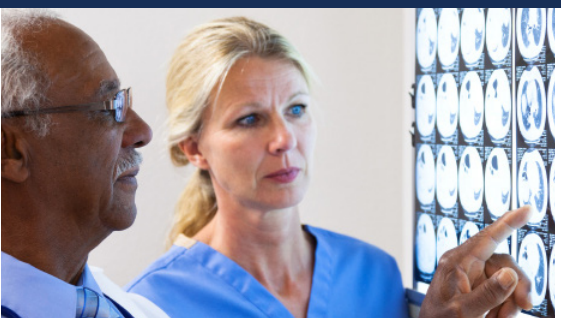
- Ideally, adequate information on older adults should be captured in the premarket clinical trials. However, if older adults are not adequately represented in pre-market clinical trials, it may be appropriate to develop a plan to collect data on older adults in the postmarket setting. This could be accomplished with post-marketing trials examining a broader population, or through collection of real world data in an observational study or registry. In certain situations, FDA may require postmarket studies and clinical trials.[15] Sponsors should prospectively discuss their plan for collecting additional information in the postmarket setting with the CDER or CBER review division or office. Postmarket data may provide clinically useful information, that when appropriate, can be added to the geriatric use section of the labeling.

[14] See footnote 12.

[15] See the draft guidance for industry *Postmarketing Studies and Clinical Trials- Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act* (October 2019). When final, this guidance will represent the FDA's current thinking on this topic.

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.

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

The National Academies of SCIENCES ENGINEERING MEDICINE

Workshops and Publications

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

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

January 22, 25, and 27, 2021

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 — sponsored by the Food and Drug Administration — will examine challenges and opportunities to improve the evidence base for treating older adults with cancer. Presentations and panel discussions will examine the root causes that limit enrollment of older adults in cancer clinical trials and strategies for improved inclusion of older adults across the drug development continuum.

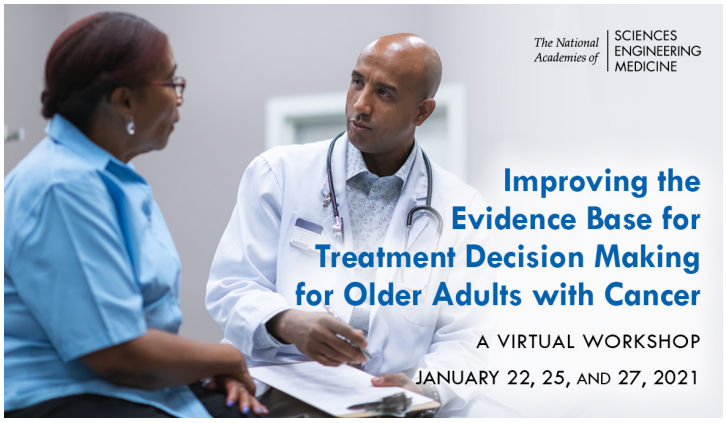
Workshop website here

Drug Research and Development for Adults Across the Older Age Span

August 5-6, 2020

This workshop follows an earlier event on on the same topic, held in 2019. Stakeholders were convened to discuss the lack of evidence about the appropriate use of drugs in older adult populations, hampering decision making about how to optimize care for older adults. Workshop presentations and discussions highlighted opportunities to better engage older adults in clinical research and strategies to generate evidence-based prescribing information for older adult populations.

Workshop videos and presentations here.



Impact of the Affordable Care Act on Cancer Prevention and Care

March 1-2, 2021

This workshop will examine the evidence base on how the Patient Protection and Affordable Care Act (ACA) has altered the landscape of cancer prevention and care delivery. The workshop will feature invited presentations and discussions on topics such as:

- The effects of coverage expansions under the ACA on access to cancer care, patient outcomes, and health disparities.
- The impact of new organizational infrastructure and their relevance to cancer research.
- The effects of payment reform demonstration projects on patient outcomes and the quality and efficiency of oncology care delivery, as well as the viability and sustainability of alternative payment models.
- Remaining evidence gaps and policy challenges and their impact on patients with cancer.
- Lessons learned from the design and implementation of the ACA that could inform future health care reform efforts.

Workshop website in development.

Addressing the Adverse Consequences of Cancer Treatment

November 9-10, 2020

Cancer care is associated with significant physical, mental, and socioeconomic consequences. This workshop, convened by the National Cancer Policy Forum in collaboration with the Forum on Aging, Disability, and Independence, examined the array of short- and long-term toxicities and adverse effects that patients may experience as a result of cancer treatment and considered opportunities to improve quality of life for cancer survivors and their families.

Workshop videos and presentation files here.

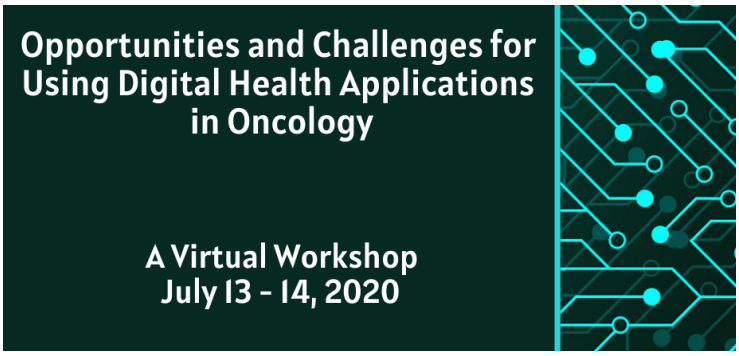
Workshops and Publications

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, convened a workshop to examine the role of digital health applications in oncology research and care. Workshop speakers discussed topics such as exemplars of novel digital health applications, including patient-facing technologies; regulatory priorities; ethical, security, governance, and payment considerations; and opportunities to improve data availability and use in EHRs and large databases.

Workshop videos and presentation files here.



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

March 2-3, 2020

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 here.

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

October 28-29, 2019

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.

Workshop videos and presentation files here.

Proceedings here.

Health Literacy and Communications Strategies in Oncology

July 15-16, 2019

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 videos and presentation files here.

Proceedings here.

Workshop overview here.

Workshop highlight videos here and here.

Developing and Sustaining an Effective and Resilient Oncology Careforce

February 11-12, 2019

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 here.

Proceedings here.

Workshop overview here.

FORUM SPONSORS

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

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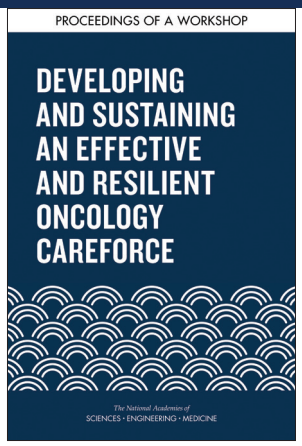
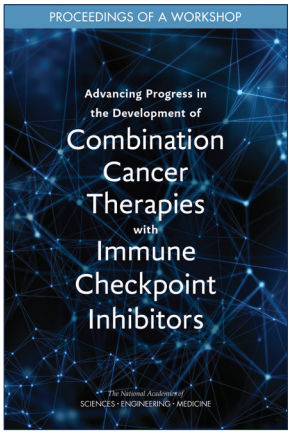
WORKSHOP PROCEEDINGS AND RELATED PUBLICATIONS





WORKSHOP PROCEEDINGS

2020

Opportunities and Challenges for Using Digital Health Applications in Oncology: Proceedings of a Workshop (In Process)

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

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

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

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

Enhancing Scientific Reproducibility 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

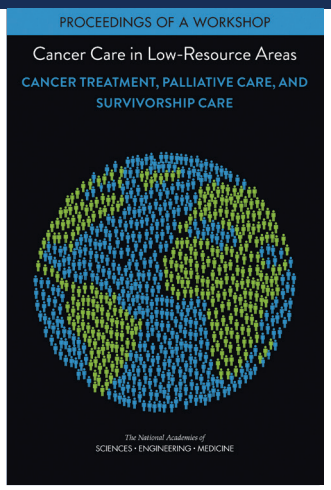
Appropriate Use of Advanced Technologies for Radiation Therapy and Surgery in Oncology: Workshop Summary

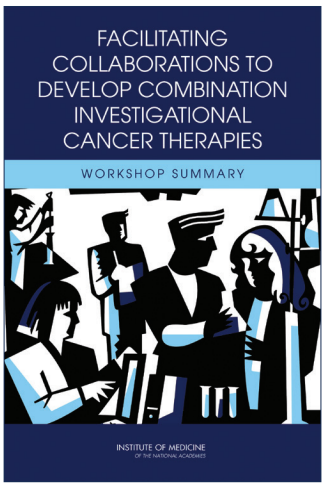
To receive updates on the National Cancer Policy Forum, visit:

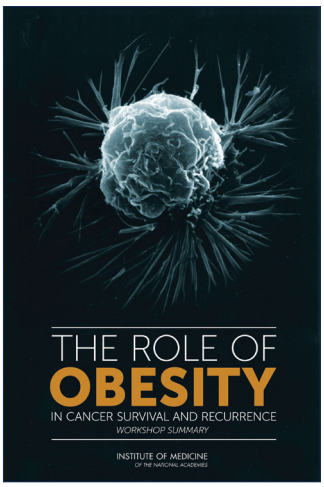
nationalacademies.org/NCPF

#NatlCancerForum

The National Academies of SCIENCES ENGINEERING MEDICINE







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: Second Workshop Summary

Sharing Clinical Research Data: Workshop Summary

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

Reducing Tobacco-Related Cancer Incidence and Mortality: Workshop Summary

2012

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

Informatics Needs and Challenges in Cancer Research: Workshop Summary

Facilitating Collaborations to Develop Combination Investigational Cancer Therapies: Workshop Summary

2011

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

Patient-Centered Cancer Treatment Planning: Improving the Quality of Oncology Care: Workshop Summary

The National Cancer Policy Summit: Opportunities and Challenges in Cancer Research and Care

Nanotechnology and Oncology: Workshop Summary

2010

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

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

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

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

2009

Assessing and Improving Value in Cancer Care: Workshop Summary

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

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

2008

Implementing Colorectal Cancer Screening: Workshop Summary

Improving the Quality of Cancer Clinical Trials: Workshop Summary

2007

Cancer-Related Genetic Testing and Counseling: Workshop Proceedings

Cancer in Elderly People: Workshop Proceedings

Implementing Cancer Survivorship Care Planning: Workshop Summary

2006

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

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

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

- Housten, A.J., C.M. Gunn, M.K. Paasche-Orlow, and K.M. Basen-Engquist. 2020. Health Literacy Interventions in Cancer: A Systematic Review. J Canc Educ. In Press.
- Schilsky, R.L., S. Nass, M.M. Le Beau, and E.J. Benz, Jr. 2020. Progress in Cancer Research, Prevention and Care. N Engl J Med. https://www.nejm.org/doi/full/10.1056/NEJMp2007839?query=featured_home.
- 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/

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- 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, and K. E. Warren. 2019. Challenges and opportunities to updating prescribing information for longstanding oncology drugs. The Oncologist 24: 1-7. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7066705/.
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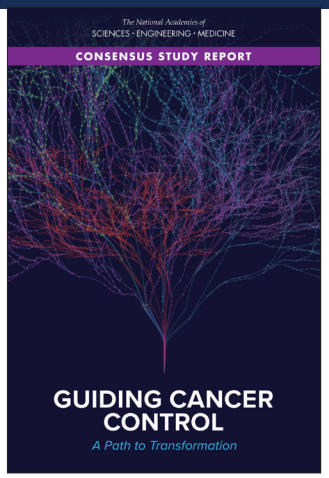
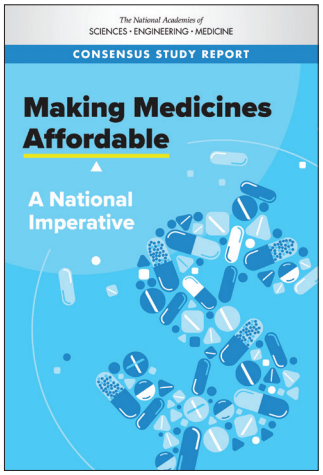
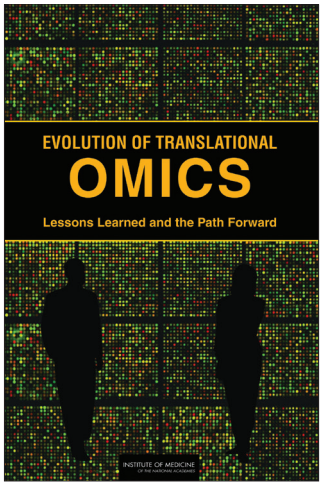
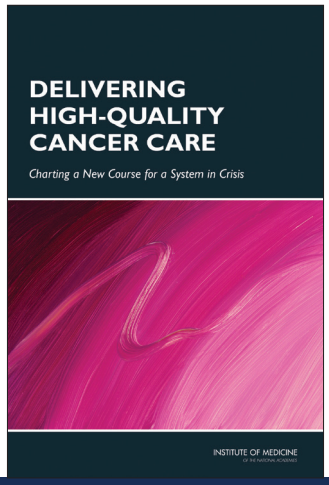
- Kline, R. M., G. B. Rocque, E. A. Rohan, K. A. Blackley, C. A. Cantril, M. L. Pratt-Chapman, H. A. Burris, and L. N. Shulman. 2019. Patient navigation in cancer: The business case to support clinical needs. Journal of Oncology Practice. Epub ahead of print JOP.1900230. https://www.ncbi.nlm.nih.gov/pubmed/31509483.
- 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.

*Accessed date for all articles is November 4, 2020.









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ABOUT THE FORUM

For more information, visit nationalacademies.org/ADIForum

#AgingDisabilityForum

Forum on Aging, Disability, and Independence

The National Academies of Sciences, Engineering, and Medicine have formed the Forum on Aging, Disability, and Independence to foster dialogue and address issues of interest and concern related to aging and disability. This includes aging and the related disabling conditions that can occur, as well as aging with an existing disability. The Forum seeks to promote bridging of the research, policy, and practice interests of the aging and disability communities to accelerate the transfer of research to practice and identify levers that will effect change for the benefit of all. Of particular concern is promoting healthy aging, independence, and community living for older adults and people with disabilities.

PERSON-CENTERED/PARTICIPANT-DIRECTED MODEL

Underpinning all aspects of achieving health and community living goals is a holistic, well-coordinated, person-centered, and participant-directed planning and implementation process. As depicted in the model below, this process should be directed by the individual in need, or by someone who either the individual has chosen or has been appropriately designated to direct and coordinate the process. The main factors that need to be coordinated include home and community settings; services and support; workforce; and financing. All of these factors exist within an environment that includes several key elements: quality; technology; research and evaluation; and policy. The Forum is focused on improving the understanding of the relationships that exist among all of these factors and examining ways to improve policies and environments that will ultimately promote independence and quality of life for older adults and people who have disabling conditions.

COORDINATION

Many systems need to work together successfully to support healthy aging, independence, and community living for people with disabilities and older adults. While both medical and social services are key to keeping older adults and individuals with disabilities in the setting of their choice in the community, these two systems are not always well connected. Similarly, in many communities there is a divide between service systems for those who are under age 65 and those who are over age 65. A goal of the Forum is to improve system integration and access to person-centered supports and services that can improve quality of life for both populations. For some individuals, this could be in the form of a designated care coordinator, whereas for others it may mean ensuring that they have information about all available resources because they choose to be their own care coordinator.

HOME AND COMMUNITY SETTINGS

Being an active member of a community is a priority for many people. A primary goal of the Forum is to foster access to services and supports that allow people with disabilities and older adults to live safely in the setting of their choosing and have the supports they need in the workplace if they would like to continue working.

SERVICES AND SUPPORT

Having access to services and supports can be critical to improving quality of life, maximizing independence, and preventing hospital re-admission. Services and supports can include assistance with dressing or cooking, social engagement,

Model for Promoting Healthy Aging, Independence, and Community Living for People with Disabilities and Older Adults

or provision of medical care. It is important to ensure that potential beneficiaries are aware of available resources and take advantage of them as appropriate.

WORKFORCE

The nation faces a growing imbalance between the supply of and demand for its health care system as the number of older adults with complex health needs increasingly outpaces the number of workers with the knowledge and skills to adequately care for them. Similarly, health care professionals are often not well-informed about proper care for people with disabilities or the problems these individuals face as they age. Fundamental reforms are needed in the ways these populations receive care, including changes to workforce education and training so that the workforce can be utilized efficiently and effectively while also providing high-quality care.

FINANCING

Although there are various sources of financing to support healthy aging and independent living services, they can be insufficient and difficult to access. Financing sources range from federal and state programs to non-profit foundations and philanthropic organizations. In addition, the private sector offers insurance (medical and long-term), and many commercial companies provide programs that can offset costs for assistive products under specified conditions. However, the individual (or family members) often finances some or, in some cases, all services that are received. Innovations in financing are needed. Preventive services are underdeveloped and "under-offered," resulting in greater expense in the long run, even though some services have found ways to cut costs while maintaining or even improving quality. The Forum examines ways to increase use of prevention strategies and provide financing that is more transparent and usable by people desiring these services.

TECHNOLOGY

Technology products have improved functioning and quality of life for people with disabilities of all ages. They can range in complexity from a calendar to coordinate which days of the week different services will be provided to devices that facilitate mobility and beyond. This is an area with many possibilities to connect the needs of consumers, regulators, businesses, and product developers. It also involves assistance in a myriad of settings, such as home, transport vehicles, medical facilities, workplaces, and community venues.

POLICY

Numerous social inequities and other barriers prevent older adults and people with disabilities, particularly those with multiple chronic conditions, from realizing their full potential for social and economic participation. The Affordable Care Act offers new opportunities, both to improve the service delivery system and to provide coverage for workers who become disabled. Yet the need for policy improvements involving equitable financing for health care, access to affordable, person-centered long-term supports and services, and workplace accommodation still remains.

RESEARCH AND EVALUATION

As policy changes are made, new technologies are developed, and the workforce adapts, evaluation and research are needed to determine whether these changes are beneficial and to validate best practices and inform future directions. Given that there are limited resources, wise use of existing data and effective coordination of research by all sectors of the nation are essential.

QUALITY

Quality is a key characteristic that encompasses all elements of the Forum's model. It is needed in any system supporting healthy aging, independence, and community living. If the systems in place are not of good quality, then they could break down, coordination could be lost, or individuals may lose trust in the people, research, and devices that are intended to help them achieve personal goals.

FORUM GOVERNANCE AND ACTIVITIES

The Forum is self-governing. Thus, the Forum membership identifies the topics it wishes to address, and with assistance from staff, develops meeting agendas and identifies workshop topics. The Forum meets 2-3 times annually and also has working groups that plan workshops and other activities. Products include workshop proceedings; cooperative projects initiated by Forum members; independently authored articles concerning Forum topics; and derivative consensus studies.

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ABOUT THE FORUM

The Forum on Drug Discovery, Development, and Translation of the National Academies of Sciences, Engineering, and Medicine was created in 2005 by the Board on Health Sciences Policy to provide a unique platform for dialogue and collaboration among thought leaders and stakeholders in government, academia, industry, foundations, and patient advocacy with an interest in improving the system of drug discovery, development, and translation. The Forum brings together leaders from private sector sponsors of biomedical and clinical research, federal agencies sponsoring and regulating biomedical and clinical research, the academic community, and patients, and in doing so serves to educate the policy community about issues where science and policy intersect. The Forum convenes several times each year to identify, discuss, and act on key problems and strategies in the discovery, development, and translation of drugs. To supplement the perspectives and expertise of its members, the Forum also holds public workshops to engage a wide range of experts, members of the public, and the policy community. The Forum also fosters collaborations among its members and constituencies. The activities of the Forum are determined by its members, focusing on the major themes outlined below.

INNOVATION AND THE DRUG DEVELOPMENT ENTERPRISE

Despite exciting scientific advances, the pathway from basic science to new therapeutics faces challenges on many fronts. New paradigms for discovering and developing drugs are being sought to bridge the ever-widening gap between scientific discoveries and translation of those discoveries into life-changing medications. There is also increasing recognition of the need for new models and methods for drug development and translational science, and "precompetitive collaborations" and other partnerships, including public–private partnerships, are proliferating. The Forum offers a venue to discuss effective collaboration in the drug discovery and development enterprise and also hosts discussions that could help chart a course through the turbulent forces of disruptive innovation in the drug discovery and development "ecosystem."

Key gaps remain in our knowledge about science, technology, and methods needed to support drug discovery and development. Recent rapid advances in innovative drug development science present opportunity for revolution- ary developments of new scientific techniques, therapeu- tic products, and applications. The Forum provides a venue to focus ongoing attention and visibility to these important drug development needs and facilitates exploration of new approaches across the drug development lifecycle. The Forum has held workshops that have contributed to the defining and establishment of regulatory science and have helped inform aspects of drug regulatory evaluation.

CLINICAL TRIALS AND CLINICAL PRODUCT DEVELOPMENT

Clinical research is the critical link between bench and bedside in developing new therapeutics. Significant infrastructural, cultural, and regulatory impediments challenge efforts to integrate clinical trials into the health care delivery system. Collaborative, cross-sector approaches can help articulate and address these key challenges and foster systemic responses. The Forum has convened a multiyear initiative to examine the state of clinical trials in the United States, identify areas of strength and weakness in our current clinical trial enterprise, and consider transformative strategies for enhancing the ways in which clinical trials are organized and conducted. In addition to sponsoring multiple symposia and workshops, under this initiative, the Forum is fostering innovative, collaborative efforts to facilitate needed change in areas such as improvement of clinical trial site performance.

INFRASTRUCTURE AND WORKFORCE FOR DRUG DISCOVERY, DEVELOPMENT, AND TRANSLATION

Considerable opportunities remain for enhancement and improvement of the infrastructure that supports the drug development enterprise. That infrastructure, which includes the organizational structure, framework, systems, and resources that facilitate the conduct of biomedical science for drug development, faces significant challenges. The science of drug discovery and development, and its translation into clinical practice, is cross-cutting and multidisciplinary. Career paths can be opaque or lack incentives such as recognition, career advancement, or financial security. The Forum has considered workforce needs as foundational to the advancement of drug discovery, development, and translation. It has convened workshops examining these issues, including consideration of strategies for developing a discipline of innovative regulatory science through the development of a robust workforce. The Forum will also host an initiative that will address needs for a workforce across the translational science lifecycle.

For more information, please visit:

NATIONALACADEMIES.ORG/DRUGFORUM

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NATIONAL CANCER POLICY FORUM

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

Workshop Dates: March 1-2, 2021

Statement of Task

A National Academies of Sciences, Engineering, and Medicine planning committee will organize and host a 1.5-day public workshop to examine the impact of the Patient Protection and Affordable Care Act (ACA) on cancer prevention and care (early detection, diagnosis, treatment, and survivorship). The workshop will feature invited presentations and panel discussions on topics that may include:

- The effects of ACA provisions such as:
  - Coverage for certain preventive care services without patient cost sharing;
  - Prohibition of exclusions for preexisting conditions;
  - Coverage of children up to age 26 on a parent's health insurance plan; and
  - State-based Medicaid expansions.
- The impact of new organizational infrastructure (e.g., the Patient-Centered Outcomes Research Institute and Centers for Medicare and Medicaid Innovation), and their relevance to cancer research.
- The effects of payment reform demonstration projects (such as accountable care organizations and the oncology medical home pilot) on patient outcomes and the quality and efficiency of oncology care delivery; as well as the viability and sustainability of alternative payment models.
- Remaining evidence gaps and policy challenges and their impact on patients with cancer.
- Lessons learned from the design and implementation of the ACA that could inform future health care reform efforts.

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:

Randall A. Oyer (Co-chair), Lancaster General Penn Medicine
Deborah Schrag (Co-chair), Harvard Medical School and Dana-Farber Cancer Institute
Cathy Bradley, Colorado School of Public Health
Robert Carlson, National Comprehensive Cancer Network
Gwen Darien, National Patient Advocate Foundation
Nicole F. Dowling, Centers for Disease Control and Prevention
Nicole Huberfeld, Boston University
Mimi Huizinga, Novartis Oncology
Roy A. Jensen, University of Kansas Cancer Center
Neal J. Meropol, Flatiron Health
Cleo A. Samuel-Ryals, University of North Carolina
Robert Winn, Virginia Commonwealth University Massey Cancer Center
Robin Yabroff, American Cancer Society

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Board on Health Sciences Policy
Board on Health Care Services

Changing the Culture of Data Management and Sharing: A Workshop

April 28-29, 2021

https://www.nationalacademies.org/our-work/changing-the-culture-of-data-management-and-sharing-a-workshop

In response to a request from the NIH Office of Science Policy, a planning committee of the National Academies of Sciences, Engineering, and Medicine will convene a two-day virtual public workshop to discuss the challenges and opportunities for researchers, institutions, and funders to establish effective data management and sharing practices. The objective of the workshop is to examine strategies, resources, and promising practices for developing and evaluating data management and sharing plans, as well as to discuss how researchers can effectively share scientific data over the course of the data life cycle.

Input will be sought from a variety of perspectives, including researchers, data repository managers, funding institutions, publishers, research participants, and other stakeholders to include a diversity of biomedical research fields and disciplines. With an emphasis on illustrative case studies, real world examples, and promising practices, potential topics may include:

- Addressing overarching strategies for managing and sharing data, taking into consideration diverse needs (e.g., human vs non-human data, type and size, data generators vs data users);
- Assessing value of shared data and the development and evaluation of data management and sharing plans, which may include discussions of:
    - best practices for repositories to collect the metrics needed to make such assessments,
    - the extent to which data value was anticipated and planned for prior to generating or sharing data, and
    - how this might inform prospective planning for sharing;
- Monitoring and evaluating data management and sharing practices, including discussion of appropriate metrics for timelines of data availability and life cycles of different types of scientific data; and
- Considering educational and other resource needs for responsible data sharing practices.

The workshop planning committee will develop the agenda for the workshop, select and invite speakers and discussants, and moderate or select moderators for the discussions. At the end of each workshop day, key points from individual speakers will be summarized and shared with the audience by a moderator. The workshop website will contain presentations from the speakers who provide the National Academies with permission to share their slides and the video of the webcast from the workshop.