Faculty Bios

Carole Baas, PhD
National Cancer Institute

Following her diagnosis with breast cancer in 2004, Dr. Carole Baas has become increasingly involved in cancer research advocacy. One of her primary responsibilities is as the National Patient Advocate for the Physical Sciences in Oncology Network (PS-ON) at the National Cancer Institute (NCI). Drawing upon her background in research and academia as well as from her personal experience with cancer—Dr. Baas has a Ph.D. in Biomedical Engineering from Texas A&M University—she volunteers as a liaison between the scientists and the cancer patient community, coordinating advocacy activities within the 20 Network Centers and Projects. She has served a variety of other roles, including Founding Editor of *Convergent Science Physical Oncology*, a peer-reviewed scientific journal; Advocate in Science for Susan G. Komen; member of the Cancer Research Advocate, Breast Cancer, and Experimental Imaging Sciences Committees at ECOG-ACRIN; RISE Legacy Advocate for the Young Survival Coalition (YSC) and member of the Council of Advisors; and member of the Baylor Research Institute IRB in Dallas, TX. She also serves on three boards at UT Southwestern: the External Advisory Board, the Community Advisory Board, and the Kidney Cancer Program Patient Council. Dr. Baas previously served as Advocate Faculty at the 2017 and 2018 ASCO/AACR Methods in Clinical Cancer Research Workshop.

Her current areas of research interest include:

- Physical sciences approaches to studying cancer (mathematical oncology, nanomedicine, biomechanics)
- Premenopausal breast cancer, especially as it relates to fertility, pregnancy and breastfeeding
- Public engagement in cancer research
- Clinical trial development
- Human research protections

Tracey Batchelor, MD
Harvard Medical School

Tracy Batchelor, MD, is the Miriam Sydney Joseph Professor of Neurology at Harvard Medical School, Neurologist-In-Chief and Chair of the Department of Neurology, Brigham and Women's Hospital, and Co-Leader of the Neuro-Oncology Program at the Dana-Farber/Harvard Cancer Center (DF/HCC). He previously served as the Executive Director of the Stephen E. and Catherine Pappas Center for Neuro-Oncology at the Massachusetts General Hospital, Associate Clinical Director of the Massachusetts General Hospital Cancer Center, and Chief of the Division of Neuro-Oncology in the Department of Neurology at the Massachusetts General Hospital. He was the Count Giovanni Armenise Professor of Neurology at Harvard Medical School from 2012-2019. His research focus is experimental therapeutics for gliomas and primary central nervous system lymphoma, with over 300 peer-reviewed publications in these areas. He is the principal investigator on four active National Cancer Institute grants, including the DF/HCC P50/SPORE award and a neuro-oncology specific K12 training grant. He is the elected chair of the NCI Brain Malignancies Steering Committee. He has also served in multiple elected leadership positions within the American Academy of Neurology and the Society for Neuro-Oncology. He has mentored over 50 neuro-oncology trainees and K12 scholars in his academic career up to this point.

Stacey Berg, MD
Baylor College of Medicine

Stacey Berg, MD, is Professor of Pediatrics and Medical Ethics & Health Policy as well as Associate Dean for Research Assurances at Baylor College of Medicine and Texas Children's Hospital. Her undergraduate degree is from Harvard, and she obtained her MD at the University of Pittsburgh School of Medicine, followed by residency in pediatrics at Children's Hospital of Pittsburgh and fellowship in Pediatric Hematology-Oncology at the National Cancer Institute. She is a pediatric oncologist specializing in the development of new anticancer drugs for children. She is also the head of the Developmental Therapeutics and Palliative Care Programs of the Texas Children's Cancer Center. She also has a strong interest in clinical trial design, biomedical ethics, and the incorporation of palliative care principles into pediatric oncology practice. She is very happy to return to the Vail Workshop after previously participating as faculty from 2010 to 2015.

Specialty areas:

- Phase I trials
- Clinical pharmacology
- IRB
- Research ethics
- Pediatric oncology palliative care

Jeff Bogart, MD
SUNY Upstate Medical University

Dr. Bogart was appointed Chair of the Department of Radiation Oncology at Upstate Medical University in 2007 after serving as an attending physician in the department since 1993 and residency director since 1997. He has served as Interim Director of Upstate Cancer Center since February 2016. Dr. Bogart has been active in clinical cancer research at the national level for more than 20 years. He currently chairs the Radiation Oncology Committee in the Alliance for Clinical Trials in Oncology, a National Cancer Institute (NCI) cooperative group, and has served in that role since 2001. His research has focused on improving outcomes for patients with localized lung cancer and areas of active clinical investigation include treatment of early and locally advanced non-small cell lung cancer, and limited stage small cell lung cancer. He is the PI on the current national phase III protocol, CALGB 30610/RTOG 0538, for limited-stage small-cell lung cancer, and he has also helped develop trials in prostate cancer, lymphoma, esophageal cancer and leukemia. He previously served on National Cancer Institute Advanced Technology Consortium for Clinical Trials Advisory Committee and the National Cancer Institute Subcommittee H. He is a coauthor of current national (ASTRO) guidelines for treatment of stage III lung cancer, and he also serves as an associate editor for the *Journal of Thoracic Oncology*.

Dr. Bogart's specialty areas and research focus include:

- Radiation dose intensity for early-stage lung cancer
- Combination therapy with novel agents for locally advanced non-small cell lung cancer
- Radiotherapy fractionation for limited-stage small-cell lung cancer
- Comparative effectiveness of surgery and radiotherapy for high-risk patients with early-stage lung cancer
- Multidisciplinary management of high-risk localized prostate cancer

Ivan Borrello, MD
Johns Hopkins University

Ivan Borrello is currently Associate Professor of Oncology and Cellular and Molecular Medicine in the Divisions on Immunotherapy and Hematologic Malignancies at Johns Hopkins University. He obtained his MD at the Medical College of Virginia, completed his Residency in Internal Medicine at the University of Chicago, and did his Fellowship in Oncology at Johns Hopkins where he then continued on as faculty. His career has been one of translational research, primarily focusing on the development of immunotherapeutic approaches in the treatment multiple myeloma. He currently has an active clinical practice in myeloma. His laboratory research interests have involved several immune-based approaches, including the development of an allogeneic GM-CSF-based universal bystander cell line that has been used in multiple disease types and settings. The vaccine work in myeloma has been in combination with adoptive T-cell therapy but also in the setting of minimal residual disease in combination with lenalidomide. His group has pioneered the development of a novel adoptive T-cell approach utilizing marrow infiltrating lymphocytes (MILs) based on their enhanced antitumor specificity enriched central memory phenotype and several other properties that demonstrate their enhanced tumor specificity, even in patients with localized solid tumors. This work has now led to exploring the use of MILs in solid tumors as well.

Specialty areas of interest include:

- Tumor vaccines in the MRD setting in myeloma
- Adoptive T-cell therapy utilizing non-gene modified MILs
- Utilizing MILs as a source for CAR-T cells
- Targeting MDSCs with PDE5 inhibition
- Enhancing clinical outcomes in myeloma through the integration of immune-based approaches

Thomas M. Braun, MD
University of Michigan

Dr. Thomas M. Braun is a Professor at the University of Michigan (UM) School of Public Health and has been a faculty member of the Biostatistics Department since 1999. He has a broad background in the design and analysis of clinical trials and clinical data specific to oncology. He is a leading expert in the design of adaptive phase I clinical trials and has also published methodology related to the analysis of longitudinal data, diagnostic tests, and competing risks. He has been the primary statistician for the UM Comprehensive Cancer Center (UMCCC) Blood and Marrow Transplantation Program and is a current member of the UMCCC Protocol Review Committee. He was previously the Analytics Lead for the Michigan Breast Oncology Quality Initiative (MiBOQI), which, through funding by Blue Cross/Blue Shield of Michigan, sought to implement policy strategies to improve the quality and safety of breast cancer treatment and outcomes in Michigan.

Specialty preferences: Stem cell transplant, leukemia, lymphoma, breast cancer

Howard A. Burris III, MD
Sarah Cannon

Howard A. "Skip" Burris III, MD, FACP, FASCO, serves as chief medical officer and president of Sarah Cannon, HCA's global cancer institute. In his roles, he leads clinical strategy and drug development research initiatives, which includes the overseeing of physician-led, patient-centric integrated cancer services. His research interests have focused on investigational therapies, particularly first in human studies. Additionally, Dr. Burris is an associate with Tennessee Oncology, PLLC. Dr. Burris graduated from the U.S. Military Academy, West Point, and received his medical degree from the University of South Alabama. He performed his residency and fellowship in hematology/oncology at Brooke Army Medical Center in San Antonio, Texas. He is an active member of the American Society of Clinical Oncology (ASCO), serving on the boards of ASCO and the Conquer Cancer Foundation, and has been elected ASCO President for 2019-2020.

Specialty areas:

- Phase I FIH clinical trials
- Novel therapies for breast cancer
- Molecular profiling
- Clinical trial operations and execution
- Mentored by Dr. Dan Von Hoff, a Vail Workshop founder

Michael A. Carducci, MD
The Johns Hopkins University School of Medicine

Michael A. Carducci, MD, is the AEGON Professor in Prostate Cancer Research at the Johns Hopkins University School of Medicine. He is the Associate Cancer Center Director for Clinical Research within the Johns Hopkins Kimmel Cancer Center. He is the Regional Research Director for the National Capital Region for the Kimmel Cancer Center. A translational researcher, Dr. Carducci directs a small laboratory program focused on bringing small molecules into early-phase clinical trials. Overall, his laboratory and clinical research focus is on the development and evaluation of new therapies for urologic cancers. Incorporation of pharmacodynamics, novel biomarkers, and targeted imaging has been a key element of many of the trials led by Dr. Carducci. To complete these studies, Dr. Carducci facilitates and brings together a multidisciplinary team of urologists, radiation oncologists, pathologists, biostatisticians, and medical oncologists. Other areas of interest include palliative and end-of-life care, survivorship, and use of patient-reported outcomes in clinical research and care.

A Fellow of the American College of Physicians and a Fellow of the American Society of Clinical Oncology, Dr. Carducci has received peer-reviewed funding for his laboratory and clinical research from the National Cancer Institute, Department of Defense, and the Prostate Cancer Foundation. Mentorship of students, fellows, and junior faculty has been another focus of Dr. Carducci's career in medicine, for which he has received numerous teaching awards. Dr. Carducci received the Michaele Christian Award and Lectureship for Oncology Drug Development at the National Cancer Institute in 2011. He is the Chair of the Genitourinary Oncology Committee of ECOG-ACRIN, and an active member of the GU Steering Committee for the NCI. Dr. Carducci is Co-Chair of the Investigational Drug Steering Committee for the NCI. He is an Associate Editor for GU Cancers for the *Journal of Clinical Oncology*.

A graduate of Georgetown University, Dr. Carducci received his medical degree with high distinction from Wayne State University School of Medicine. He completed an internal medicine internship, residency, and chief residency at the University of Colorado Health Sciences Center. He went on to complete medical oncology and research fellowships at the Johns Hopkins Oncology Center at Johns Hopkins Hospital.

Specialty preferences:

- GU cancers
- Phase 1 trials
- Cooperative Group trials
- Palliative care

Richard Chappell, PhD
The University of Wisconsin Madison Medical School

Education:
The University of Chicago, Chicago, IL
1988: MS in statistics. Thesis topic: Fitting bent lines to data with an application to allometry
1990: PhD in statistics. Thesis topic: Analysis and collection of interval censored truncated data. Advisors: Wing Hung Wong and Paul Meier.

The University of Texas at Austin
1983: BSc in mathematics, specializing in statistics with a minor in geology

Research interests/specialty areas:

- Clinical trials
- Non-inferiority trials
- Dose-escalation trials
- Radiation oncology
- Radiobiologic modeling

History with the workshop: Faculty 2007-2014, 2018

Ezra Cohen, MD, FRCPSC, FASCO
UC San Diego Health

Ezra Cohen, MD, is co-Director of the San Diego Center for Precision Immunotherapy and an internationally renowned translational researcher. A physician-scientist, Dr. Cohen led an independently funded laboratory interested in mechanisms of action of novel therapeutics. He has made major contributions to targeted and immunotherapy. His research has received peer-reviewed funding in the study of epidermal growth factor receptor inhibitors, cell therapy, and immunotherapy in head and neck cancer. He has made major contributions to the understanding of critical signaling pathways, integration of novel agents into standard of care, and definition of mechanisms to overcome resistance to drug therapy. He has also recently codeveloped a personalized neoantigen vaccine using unique cancer
mutations to boost an antitumor immune response.

Dr. Cohen is Associate Director for Translational Science and leader of the Solid Tumor Therapeutics research program at Moores Cancer Center. He brings his expertise and preeminent reputation in head and neck cancer research and patient care to solid tumor therapeutics. Among other roles, he is chair of the Protocol Review and Monitoring Committee (PRMC) and serves as a member of the Cancer Council, and the Cancer Center's Executive Committee.

Dr. Cohen recently served as editor-in-chief of *Oral Oncology*, the highest-impact specialty journal in head and neck cancer, and currently serves as senior editor for *Clinical Cancer Research*. He has been the principal investigator on multiple studies of novel agents in head and neck cancer and other solid tumors in all phases of development including chemoprevention, phase I, II, and III trials. Dr. Cohen has authored more than 170 papers and has presented his research at national and international meetings. In addition, he has served as a grant reviewer for the NIH, American Association for Cancer Research, American Society of Clinical Oncology, and the Ontario Institute for Cancer Research.

Dr. Cohen completed residencies in Family Medicine at the University of Toronto and in Internal Medicine at Albert Einstein College of Medicine. He completed a Hematology/Oncology fellowship at the University of Chicago, where he was named chief fellow. Prior to his arrival in San Diego, Dr. Cohen was Co-Director of the Head and Neck Cancer Program, Associate Director for Education and Program Director for the Hematology/Oncology Fellowship at the University of Chicago Comprehensive Cancer Center. A dedicated educator, Dr. Cohen also mentored and developed young faculty in his program.

Deborah Collyar, President
Patient Advocates In Research (PAIR)

Deborah Collyar has been a leader in patient engagement and advocacy since her first cancer diagnosis. She utilizes her business leadership, IT, and communication skills to bridge research gaps between scientists, medical providers, and patients. Deborah founded the Patient Advocates in Research (PAIR) international network in 1996, "where research meets reality," and she consults with the health research community. Deborah has infused hundreds of patient advocates into research programs, while both delivering a variety of advocacy training and delivering innovative ways to gather input from thousands of patients. Her work encompasses many diseases, programs, and policies at grassroots, national, and international levels, and emphasizes patient issues throughout early development and protocols, through recruitment, retention, and results reporting. Deborah also serves as a consultant to Health Literacy Media (HLM) in their Clearly Communicating Clinical Trials (C^3T) program. Deborah encourages innovation in clinical trials and health care delivery. She has been a key stakeholder in pivotal projects with the NIH, NCI Clinical Trials Network (NCTN), ASCO, AACR, Clinical Trials Transformation Initiative (CTTI), Center for Medical Technology

Policy (CMTP), DIA, Institute of Clinical and Economic Review (ICER), Metastatic Breast Cancer Alliance (MBCA), Multi-Regional Clinical Trials Center (MRCT), Oncology Research Information Exchange Network (ORIEN), Society for Immunotherapy in Cancer (SITC), academic institutions, companies, and international consortia. She is a speaker, blogger, author, grant team member, trainer, and faculty at professional workshops such as the Vail Methods in Clinical Research and the SITC Winter School, and often presents the patient perspective at professional meetings. She and her husband have survived 3+ cancers, and they work with multiple communities and patients.

Specialty areas:

- Trial design and clinical trial development (since 1994); Vail faculty (2002, 2018-current)
- Clear health-literate communication for providers and patients (e.g., recruitment, retention, and results)
- Strategy and building collaborative partnerships in many fields, including health policy
- Publication leadership, including editorial board positions and review for several journals
- Genomics and other –omics, biospecimens and biomarkers, and immunotherapy

Sean Devlin, PhD
Memorial Sloan Kettering Cancer Center

Dr. Devlin is an Assistant Attending Biostatistician at Memorial Sloan Kettering Cancer Center. In this role, he serves as the primary collaborative biostatistician for researchers in the Clinical Leukemia, Bone Marrow Transplant, and Myeloma services. He works on the design and analysis of clinical trials and retrospective studies, as well as the analysis of preclinical and correlative studies. Dr. Devlin serves as a chair of the Biostatistics Protocol Review Committee at MSKCC.

- Biostatistics Trainee at Vail in 2012 and on faculty since 2017
- Expertise in leukemia, multiple myeloma, transplantation, and cellular therapy
- Methodologic interests are in the development of high-dimensional regression methods for disease risk, and survival analysis

Adam P. Dicker, MD, PhD, FASTRO
Thomas Jefferson University-Jefferson Health

Adam P. Dicker, MD, PhD, FASTRO, FASCO, is a leading expert in prostate cancer and brain tumors with a focus on digital health and translational sciences applied to oncology. He coordinates and leads an interdisciplinary team of oncologists, immunologists, physicists, data scientists, nurses, and behavioral scientists participating in a multidisciplinary effort to define fundamental mechanisms and targets for cancer treatment and efficiently translate them to effective innovations for patients. Their work has resulted in the establishment of parameters for quality assurance in radiation oncology, novel therapeutic clinical trials utilizing targeted therapies, innovative models to evaluate radiation modifiers, FDA approval of a genomic signature for management of prostate cancer, and use of wearables combined with patient-reported outcomes to identify and mitigate treatment toxicity.

Dr. Dicker holds leadership roles, including Co-Chair Translational Science and Digital Health committees for NRG Oncology (nrgoncology.org); Chair Emeritus, Integration Panel for the Prostate Cancer Research Program-Department of Defense; and Radiation Oncology Co-Chair, NCI Genitourinary Cancers Steering Committee Prostate Cancer Task Force. He actively participates on the National Cancer Institute as Co-Chair, NCI Clinical Trials and Translational Research Advisory Committee Ad hoc Working Group on Radiation Oncology, Investigational Drug Steering Committee, and National Clinical Trial Network Core Correlative Sciences Committee. Since 2018, Dr. Dicker has led a university-wide effort in Digital Health and Data Science, as the Director of the Jefferson Center for Digital Health, using the convergence of mobile technology, platforms, networks, and machine learning to improve the lives of patients. It houses medical student and graduate degree programs and postgraduate education, coordinates research, and develops critical industry partnerships related to digital health across the Jefferson Health System. The Center for Digital Health plays a pivotal role in the promotion, resourcing, design, and coordination of clinical and evaluative digital health research at Jefferson.

Dr. Dicker serves on numerous American Society for Radiation Oncology and American Society of Clinical Oncology committees and on the editorial boards of *Clinical Cancer Research, JCO Clinical Cancer Informatics,* and *JCO Precision Oncology*. He serves as Enterprise Senior VP, Professor and Chair of Radiation Oncology at Thomas Jefferson University-Jefferson Health. He has mentored over 40 students, residents, post-docs and fellows. Dr. Dicker received his BA from Columbia College and his MD and PhD (Molecular Pharmacology) from Cornell University. He received his postgraduate training at Memorial Sloan-Kettering Cancer Center after a surgical internship.

Maura N. Dickler, MD
Lilly Oncology

Dr. Maura Dickler presently serves as the Vice President of Oncology, Late Phase Development at Eli Lilly and Company. Maura joined Eli Lilly in May 2018 after working for 20 years as a breast cancer medical oncologist at Memorial Sloan Kettering Cancer Center (MSKCC) in New York. She attended The College at the University of Chicago and earned her MD degree at the University of Chicago Pritzker School of Medicine. She completed her internship and residency training at the University of Chicago Hospitals, followed by a fellowship in hematology and medical oncology at MSKCC. In 1998 she joined the faculty and was promoted to an Associate Member on the Breast Medicine Service and an Associate Professor of Medicine at the Weill Medical College of Cornell University. She also served as Section Head of the Endocrine Therapy Clinical Research Program and Interim Head of the Breast Medicine Service from 2015-2017. Dr. Dickler is board certified in medical oncology.

While at MSKCC, her clinical research focused on developing new therapeutic strategies for the treatment of estrogen receptor (ER)-positive breast cancer. This included the development of biologically rational combinations of drugs targeting important pathways such as the ER, VEGFR, HER2. and PI3K pathways. In addition, she developed agents inhibiting CDK 4 and 6 of the cell cycle. She joined Lilly in 2018 to lead late-phase development in the Oncology Business Unit, and she oversees the research and development of several therapeutic agents including Verzenio, Cyramza, Loxo 292, and pegilodecakin.

Emily Dressler, PhD
Wake Forest School of Medicine

Dr. Emily Dressler is an Associate Professor in the Department of Biostatistics and Data Science at Wake Forest School of Medicine. She leads the Biostatistics core of the Wake Forest NCI Community Oncology Research Program (NCORP) and is part of the Biostatistics Shared Resource at their NCI-designated Comprehensive Cancer Center. She was previously in the Division of Cancer Biostatistics at the University of Kentucky Markey Cancer Center and received her PhD in Biostatistics from the Medical University of South Carolina in 2010.

Current research Interests:

- Adaptive clinical trial designs in oncology
- Phase I continual reassessment models
- Interim monitoring strategies
- Mixed efficacy and toxicity designs for immunotherapies/molecularly targeted agents

History with this Workshop:

- Biostatistics trainee – 2012
- Participant in Methods in Cancer Biostatistics Workshop: Clinical Trial Designs for Targeted Agents – 2015
- Faculty – 2017 to present

Ivy Elkins, MBA
LUNGevity

Ivy Elkins is one of the cofounders of the EGFR Resisters, a patient-driven initiative to understand and improve treatments for EGFR+ lung cancer through collaborations with researchers and advocacy groups. She is a dedicated advocate for lung cancer research, having served three times as a consumer reviewer for the Department of Defense Lung Cancer Research Program and twice completed the AACR Scientist-Survivor program. This will be Ivy's third year acting as advocate faculty for the ASCO/AACR Methods in Clinical Cancer Research Workshop. Ivy's primary areas of research focus include metastatic lung cancer, clinical trials, driver mutations/molecular testing, drug resistance, and survivorship. In addition, Ivy serves on both the Patient Advocacy committee for IASLC and on the Cancer Patient Advisory Council at the University of Chicago. She also writes for lungcancer.net and frequently

shares her patient perspective with the media and with pharmaceutical companies involved in lung cancer treatments.

Ivy has been involved with the LUNGevity Foundation as a patient advocate since her diagnosis in December 2013 with EGFR+ stage IV lung cancer that had metastasized to her bones and brain. She receives her treatment at the University of Chicago and lives in the Chicago suburbs with her husband Ben and her two teenaged boys. She has an undergraduate degree in English from Princeton University and a Master's in Business Administration from the Wharton School at the University of Pennsylvania.

Gerard Evan, PhD, FRS, FMedSci
University of Cambridge

Professor Evan's research focuses on the molecular basis of cancer. To address this problem, he has developed a novel class of genetically engineered mouse in which individual oncogenes and/or tumour suppressor genes may be systemically toggled off and on, reversibly and at will, in vivo. In this way the most effective therapeutic targets can be identified. Using two such mouse models, his research has directly ascertained the therapeutic impact, efficacy and side effects of Myc inhibition and p53 restoration – two key targets involved in the process of cancer cell replication and regulation - establishing both mechanism of action and therapeutic index.

Professor Evan serves as Member of the Scientific Advisory Board at Ensemble Discovery Corporation, is a Gerson and Barbara Bass Baker Distinguished Professor of Cancer Biology at the University of California San Francisco, Co-leader of the Cell Cycling and Signaling Program at the UCSF Comprehensive Cancer Center, which he helped create in 1999 and is Head of the Department of Biochemistry at the University of Cambridge.

Gerard Evan received his BA in Biochemistry from the University of Oxford (St. Peter's College) in 1977 and his PhD in Molecular Immunology in 1981 from the University of Cambridge (King's College). He worked in the laboratory of J. Michael Bishop at UCSF from 1982-84 and then returned to the UK to become an Assistant Member of the Cambridge Branch of the Ludwig Institute for Cancer Research and a Research Fellow of Downing College, Cambridge. In 1988 he joined the Imperial Cancer Research Fund (ICRF) Laboratories in London as a Senior Scientist (1988-90) and then Principal Scientist (1990-1999). He was awarded the Pfizer prize in Biology in 1995, and in 1996 was elected as the Royal Society's Napier Professor of Cancer Research. In 1999 he was elected a Fellow of the UK Academy of Medical Sciences and later that year appointed to the Gerson and Barbara Bass Baker Distinguished Professor of Cancer Biology at the University of California, San Francisco. He was elected to the Royal Society in 2004, to the Neal Levitan Research Chair of the Brain Tumor Society and, in 2006, became a Senior Scholar of the Ellison Medical Research Foundation for Aging. In 2009, he was elected to the Sir William Dunn Chair of Biochemistry in the University of Cambridge where he is now Head of the Department of Biochemistry.

Margaret Foti, PhD, MD (hc)
American Association for Cancer Research

Dr. Foti is the Chief Executive Officer of the American Association for Cancer Research (AACR). Located in Philadelphia, PA, the AACR is the oldest and largest cancer organization in the world dedicated to the conquest of cancer. Dr. Foti holds a BA, MA, and PhD from Temple University in Philadelphia, and has been awarded several Honorary Doctorate degrees; one in Medicine from the University of San Pablo CEU in Madrid in June 2009, another in Medicine and Surgery from the University of Catania, Catania, Italy in July 2008, and a third in Medicine and Surgery from the University of Rome in 2003 for contributions to cancer research worldwide. She previously served as Managing Editor of the Cancer Research journal and as Publisher for AACR for many years. Active in a wide variety of professional publishing organizations, Dr. Foti is a Past President of the Society for Scholarly Publishing and the Council of Science Editors.

During Dr. Foti's tenure, the AACR has developed a dynamic and diverse membership of over 35,000 members in more than 90 countries. She contributes to numerous cancer research enterprises and organizations and is a member of the Executive Committee for the Friends of Cancer Research; Council Member for the European Association for Cancer Research; and Past President of the National Coalition for Cancer Research, to name a few. Dr. Foti has received numerous national and international awards for her commitment and contributions to cancer research, including: MGH's 100 Amazing People Award as a champion of the global cancer community, Children's Champion Award from the Children's Hospital of Philadelphia, Ellen V. Sigal Advocacy Leadership Award from Friends of Cancer Research, Morton M. Kligerman Visiting Professorship Award from the University of Pennsylvania, Stanley P. Reimann Honor Award from Fox Chase Cancer Center, Distinguished Partner in Hope Award during the Annual Colorectal Cancer Conference hosted by the Abramson Cancer Center of the University of Pennsylvania, Research!America's Raymond and Beverly Sackler Award for sustained national leadership, European CanCer Organisation's Lifetime Achievement Award for outstanding contributions to cancer; the Inaugural Kripke Legend Award for significant contributions to the advancement and promotion of women in the cancer field; and ASCO's Special Recognition Award for her instrumental role in the development of this important Workshop and providing vital links between translational scientists and clinicians. In 2008, Dr Foti expanded the role of the AACR to a major grant-giving organization as Scientific Partner for Stand Up To Cancer (SU2C), a national translational cancer research initiative, that has funded over 236 million dollars into the cancer field.

Dr. Foti has served on the Vail Workshop Faculty since its inception, and worked with Dr. Daniel D. Von Hoff, Past President of AACR and Founder of the Vail Workshop, to help develop his concept for this Workshop, which has trained over 2400 clinical researchers in clinical trial design in the United States and abroad.

Specialty preferences: Association management; publishing; government relations; foundation support; administration

Thomas Gajewski, MD, PhD
University of Chicago

Thomas Gajewski, MD, PhD is Professor in the Departments of Pathology and Medicine. He oversees the melanoma oncology clinic, is Leader of the Immunology and Cancer Program at the University of Chicago Comprehensive Cancer Center, and directs the Human Immunologic Monitoring core facility.

His laboratory studies the molecular and cellular regulation of T lymphocyte activation and differentiation, and in turn applies this information to preclinical and clinical efforts to promote anti-tumor immunity in vivo. Dr. Gajewski is committed to investigating and developing new treatments for patients with melanoma, with a special interest in the development of immunotherapies against the disease. He also leads development of immune-based therapies for other cancers, using new laboratory data on how the immune system is regulated to develop novel clinical trials.

Dr. Gajewski has published more than 200 papers on these subjects, has served on numerous NIH grant review panels, is an editor for Cancer Research and Journal for Immunotherapy of Cancer, is on the Program Committees for the American Society for Clinical Oncology (ASCO) and the American Association for Cancer Research (AACR), and is past president of the Society for Immunotherapy of Cancer. He was recently awarded the first American Cancer Society-Jules L. Plangere Jr. Family Foundation Professorship in Cancer Immunotherapy.

As his laboratory work leads to new potential immunotherapies for cancer, Dr. Gajewski is involved with several early biotech companies. He scientific co-founder of Jounce Therapeutics, and has licensing arrangements with Aduro Biotech and Evelo, a new company focused on the microbiome and cancer.

Karyn A. Goodman, MD
University of Colorado Cancer Center

Dr. Karyn Goodman is the David F. and Margaret Turley Grohne Chair in Clinical Cancer Research and the Associate Director of Clinical Research for the University of Colorado Cancer Center. She is a Professor of Radiation Oncology and Vice-Chair of Clinical Research in the Department of Radiation Oncology. She specializes in cancers of the gastrointestinal tract and serves as the Co-Chair of the National Cancer Institute (NCI) Gastrointestinal Steering Committee. Dr. Goodman received her undergraduate and medical degrees from Stanford University and an M.S. in Epidemiology from the Harvard School of Public Health. She completed residency training at Memorial Sloan-Kettering Cancer Center and attended the Vail Workshop as a senior resident in 2003. She was on the faculty at

Stanford University from 2004-2006, at MSKCC from 2007-2015, and has been at the University of Colorado since then.

Dr. Goodman is an internationally recognized expert in gastrointestinal cancers and has served in numerous leadership roles on ASTRO, ASCO, and NRG committees as well as multiple national committees evaluating best practices and quality of care in radiation oncology. She serves as the national Radiation Oncology principal investigator of the RTOG/NRG 0848 study, a phase III trial evaluating the use of postoperative radiotherapy for pancreatic cancer. She is the national Study Chair for the Alliance Cooperative Group phase II trial (CALGB 80803) investigating PET scan-directed therapy for esophageal cancer. She developed several investigator-initiated trials evaluating the use of new radiotherapy techniques for gastrointestinal tumors and has submitted two patents for the development of brachytherapy applicators. She received an ASCO Young Investigator Award as well as multiple grants to support her research in radiation oncology. She has published over 100 peer-reviewed articles, review articles, and chapters.

Dr. Goodman's interests include:

- Stereotactic Body Radiotherapy (SBRT) for pancreas and liver malignancies
- Evaluating patient-reported outcomes and quality of life during and after RT
- Combining immunotherapy with SBRT for GI cancers
- Imaging as a biomarker for treatment response
- Motion management during focal delivery of RT

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

Dr. Roy Herbst is Ensign Professor of Medicine, Professor of Pharmacology, Chief of Medical Oncology, Director of the Thoracic Oncology Research Program, and Associate Director for Translational Research at Yale Cancer Center (YCC) and Yale School of Medicine, New Haven, CT. Dr. Herbst has worked over several decades as a pioneer of personalized medicine and immunotherapy to identify biomarkers and bring novel targeted treatments and immunotherapies to patients, serving as principal investigator for numerous clinical trials testing these agents in advanced stage lung cancers. This work led to the approval of several therapies (such as gefitinib, cetuximab, bevacizumab, axitinib, atezolizumab, and pembrolizumab), which have revolutionized the field and greatly enhanced patient survival. His work on "umbrella" trials has galvanized the field of targeted therapy and cancer drug approvals at the FDA. Nationally, he is at the forefront of personalized medicine and works closely with public-private partnerships to develop large clinical studies, such as Lung-MAP. He testified on this before the House of Representatives 21st Century Cures committee and served as a prominent figure in this area as a member of the NAM Policy forum for 9 years. The NCI Lung SPORE he leads has identified new mechanisms of sensitivity and resistance to immunotherapy.

Dr. Herbst is a highly respected clinician- scientist who has been a champion of translational medicine for decades, recently authoring a high-profile review of the 20-year progress in lung cancer. He has also been a major proponent of efforts to promote tobacco control and regulation (including e-cigarettes), authoring multiple policy statements and leading frequent Capitol Hill briefings. Dr. Herbst has authored or coauthored more than 300 publications, including peer-reviewed journal articles, abstracts, and book chapters. His work has appeared in many prominent journals, such as the *Journal of Clinical Oncology, Clinical Cancer Research, Lancet,* and the *New England Journal of Medicine.* Work published in *Nature* was awarded the 2015 Herbert Pardes Clinical Research Excellence Award by the Clinical Research Forum.

Dr. Herbst was a member of the National Cancer Policy Forum, for which he organized an IOM meeting focused on policy issues in personalized medicine. He is a member of the American Association of Cancer Research, where he chairs the Tobacco Task Force, as well as the American Society of Clinical Oncology. He is a fellow of the American College of Physicians and an elected member of the Association of American Physicians. He is vice chair for developmental therapeutics for Southwestern Oncology Group's (SWOG) Lung Committee. In 2015, his team at Yale was awarded a Lung Cancer SPORE by the NCI, and he serves as a principal investigator for a AACR/Stand Up To Cancer Dream Team grant. For his lifetime achievement in scientific contributions to thoracic cancer research, Dr. Herbst was awarded the 2016 Paul A. Bunn, Jr. Scientific Award by the International Association for the Study of Lung Cancer at IASLC 17th World Conference on Lung Cancer in Vienna, Austria.

Specialty areas:

- Master protocols
- Immuno-therapy
- Targeted therapy
- Thoracic oncology
- Mentorship

Dawn L. Hershman, MD
Herbert Irving Comprehensive Cancer Center

Dr. Hershman is a Professor of Medicine and Epidemiology with Tenure and is Director of the Breast Cancer Program of the Herbert Irving Comprehensive Cancer Center. She has developed nationally recognized expertise in breast cancer treatment, prevention, survivorship, late effects of cancer therapy, health outcomes, and health disparities research. She was awarded career development awards from the American Society of Clinical Oncology (ASCO) and the National Cancer Institute (K07). She has subsequently received research funding from the American Cancer Society, ASCO, Department of Defense, Susan Komen Foundation, Breast Cancer Research Foundation, AVON Foundation, and the NCI. In addition, she was selected to be a Komen Scholar.

She has mentored numerous faculty members who have been granted mentored career development awards. She has a strong publication record with over 400 papers, including many in high-profile journals, with many receiving national press coverage. She has several national leadership roles in oncology. She is the Vice-Chair of the SWOG NCORP research base and 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 the quality of care committee and the publications committee. She is Co-Chair of the CancerLinq Research and Publications Committee. She serves on the breast cancer and the cancer care delivery steering committees of NCI. She is on the editorial board for the *Journal of Clinical Oncology* and is an Associate Editor of the *Journal of the National Cancer Institute*.

Dr. Hershman 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 is a Komen Scholar and currently has a Conquer Cancer Foundation Research Professorship in Breast Cancer Comparative Effectiveness Research.

Manuel Hidalgo, MD, PhD
Weill Cornell Medicine

Dr. Hidalgo is a clinically active oncologist whose research, funded by the National Cancer Institute and the European Research Council, focuses on new drug development in pancreatic cancer. He has published more than 220 articles in top-tier journals including the Journal of Clinical Oncology, Clinical Cancer Research and Cancer Discovery, where he also serves as a scientific editor. Dr. Hidalgo is a member of the American Society of Clinical Oncology (ASCO), the American Association of Cancer Research (AACR) and the European Society of Medical Oncology. He has received multiple awards from ASCO, including a Career Development Award, an AACR-Bristol-Myers Squibb Oncology Fellowship in Clinical Research, as well as international honors for his work in cancer.

Dr. Hidalgo received his medical degree in 1992 from the University of Navarra in Pamplona, Spain, and a doctorate in infectious diseases and cancer from the University Autónoma of Madrid, Spain. He completed his residency training in medical oncology at the Hospital 12 de Octubre in Madrid and a fellowship in medical oncology at the University of Texas Health Science Center in San Antonio, where he also served as an assistant professor of medicine. In 2001, he joined Johns Hopkins University as an associate professor of oncology and in 2003 became director of the gastrointestinal oncology program at the Kimmel Comprehensive Cancer Center. In 2009, he became director of the clinical research program at the Spanish National Cancer Research Centre (CNIO) in Madrid and vice director of translational research in 2011. Since 2015, he has served as a faculty member at Harvard Medical School and chief of the Division of Hematology and Oncology at Beth Israel Deaconess Medical Center in Boston. In March of 2019 he was named chief of the Division of Hematology and Medical Oncology in the Weill Department of Medicine at Weill Cornell Medicine and New York-Presbyterian/Weill Cornell Medical Center.

Elizabeth Hill, PhD
Medical University of South Carolina

I am a Professor of Biostatistics at the Medical University of South Carolina (MUSC) and the Director of the Biostatistics Shared Resource (BSR) at the Hollings Cancer Center (HCC) of MUSC. I graduated from Emory University in 2002 with a PhD in Biostatistics and joined the faculty of MUSC in 2003 in the Department of Public Health Sciences. I have been a member of the HCC BSR since 2007 and was appointed Director in 2017. In my 10+ years as a BSR member, I have collaborated with MUSC cancer center investigators spanning the oncology research continuum, from designing bench experiments and early-phase clinical trials, to analyzing data from laboratories and large-scale epidemiologic databases. I have a strong track record of continuous funding as coinvestigator with numerous cancer center investigators, and have contributed to over 85 publications, the majority appearing in cancer or cancer-related journals. I have participated in NIH special emphasis review panels including SPORE and NCORP applications and have been a continuous member of ASCO's Conquer Cancer Foundation review panel for Young Investigator and Career Development awards since 2013. Recently I was appointed a member of NCI's Clinical Oncology study section. My statistical methodology research interests have been motivated by problems I've encountered working with cancer center collaborators and have focused on:

- Statistical methods development in biomarker discovery
- Analytic methods for tandem mass spectrometry data
- Analytic methods for MALDI imaging mass spectrometry data
- Analytic methods for multiplex immunoassay data
- Latent class analysis

Kay Kays
Independent Advocate

I am a 20+ year pancreatic cancer survivor... having survived initial dx, locally advanced, and 2 metastases. My journey involved becoming patient active with my cancer at the Wellness Community-Az, initiating my research patient advocacy as a host of the 1st pancreatic cancer network in Az. I saw the need for an educational bridge between patients <-> research... and began seeking training and resources. Serving as a patient advocate with the SPORE in GI Cancer at the AZ Cancer Center was a first step in

beginning to participate locally and nationally as a GI patient research advocate. My participations have included SPORE Patient Advocate Research Team (PART), Alliance for Oncology Clinical Trials (formerly CALGB), Gateway for Cancer Research Scientific Counselors Patient Research Advocate, Research Advocacy Network/Tissue Think Tank, Wellness Community Board of Directors, Translational Genomics Research Institute/PCRT, Department of Defense-Pancreatic Cancer, National Institute of Health Patient Centered Outcome Research Institute, American Cancer Society, and the Pancreatic Cancer Action Network. Clinical trials and tissue donation are my main interests in helping cancer research move successfully forward for patients. I initiated and served as the Deputy Director with AzMN in a grassroots 1-yr. grant (Tissue Donor Awareness Project or TDAP) to educate patients about "What is tissue" and "Why tissue is important for cancer research." I am a faculty member of Methods in Clinical Research, addressing public language in clinical research studies for patient understanding. My dissemination of cancer research to patients is always a 2-way street of learning, and I am able to represent cancer patients at the grant review table with up-to-date information for accrual and quality of life from the real world of cancer.

Specialty preferences: GI patient advocate—pancreas, colon, esophageal, liver, and tissue collection

Tari A. King, MD
Harvard Medical School

Dr. Tari A. King is the Anne E. Dyson Associate Professor of Surgery in the Field of Women's Cancers at Harvard Medical School, the chief of the Division of Breast Surgery and the associate chair of multidisciplinary oncology in the Department of Surgery at Brigham and Women's Hospital, and the chief of breast surgery at Dana-Farber/Brigham and Women's Cancer Center. She is also the director of the Breast Cancer Personalized Risk Assessment, Education and Prevention (B-PREP) Program at Brigham and Women's Hospital. Dr. King received her medical degree from University of Colorado Health Sciences Center and completed a general surgery residency at Ochsner Clinic Foundation Hospital (now Ochsner Medical Center) in New Orleans. Dr. King completed both a surgical research fellowship and a breast surgery clinical fellowship at Memorial Sloan Kettering Cancer Center. Her research has focused on the molecular genetics of lobular carcinoma in situ and the role of surgery in metastatic breast cancer.

Specialty areas:

- Local-regional management of breast cancer with a focus on molecular subtype
- Breast cancer prevention in high-risk populations

Mark Krailo, PhD
University of Southern California

Mark Krailo, PhD, is a Professor of Research in the Department of Preventive Medicine at the University of Southern California and a Senior Statistician with Children's Oncology Group. He earned his PhD in statistics from the University of Waterloo, Waterloo, Ontario, Canada. Dr. Krailo has been a member of the Statistics Department of Children's Oncology Group and one of predecessor groups for over 35 years. He is also a member of the Malignant Germcell Tumor Consortium (MaGIC) and the Childhood Hepatic tumor International Collaboration (CHIC). In addition to his role as a statistician on phase I, II, and III studies, Dr. Krailo serves as a member of the data and safety monitoring committee for the New Approaches to Neurobastoma Therapy (NANT) consortium and is Chair of the data and safety monitoring committee for the California Cancer Consortium (CCC). This is his eighth year as a faculty member at Vail.

Specialty preferences:

- Clinical trials, particularly those of pediatric oncology
- Epidemiology of cancers of children and young adults as well as breast cancer

Shing M. Lee, PhD
Columbia University

Dr. Lee received her Master's in Biostatistics from Johns Hopkins University and her PhD in Biostatistics from Columbia University. Her research interests are in the design and conduct of early-stage cancer clinical trials. She is particularly interested in the lapses of current trial designs for determining the optimal dose for targeted and immunotherapeutic agents; methods for summarizing and accounting for adverse event grades, types, and duration in clinical trials; the development of algorithms that can simplify the implementation of these novel designs in practice; and the analysis and summary of adverse event data. In addition, Dr. Lee serves as the director for the Biostatistics, Epidemiology and Research Design Resource of the Clinical and Translational Award at Columbia University. In that role, she has assisted numerous investigators from a variety of medical disciplines in the design, conduct, and analysis of clinical studies and has mentored many fellows and junior faculty members. This is her third year as faculty in AACR/ASCO Vail Workshop on Methods in Clinical Cancer Research, and she is a past faculty of the AACR Methods in Cancer Biostatistics: Clinical Trial Designs for Targeted Agents workshop.

Specialty interests:

- Dose-finding clinical trials
- Trials of targeted agents and immunotherapies
- Analysis and interpretation of adverse event and symptom data

Stuart M. Lichtman, MD
Memorial Sloan Kettering Cancer Center

I am a medical oncologist and member of the Gynecologic Oncology Disease Management Team at
Memorial Sloan Kettering Cancer Center and participate in the 65+ Clinical Geriatrics Program. My
main research interest is in the treatment and evaluation of older cancer patients. In ASCO, I have been on the Clinical Practice Committee and Scientific Program Committee, am currently on the Health Disparities Committee Working Group on Addressing Cancer Disparities Among Older Adults, and chair the Organ Dysfunction Section of the Modernizing Clinical Trials Eligibility Project and the Scientific Education Committee. I am the Associate Editor for Geriatric Oncology of the ASCO Post. I have been a guest editor of special editions of the *Journal of Clinical Oncology* devoted to geriatric oncology in 2007 and 2014. I am involved in a number of research organizations, including the Elderly Taskforce of the Gynecologic Oncology Group (currently NRG), Gynecologic Cancer Steering Committee of the NCI, and the Cancer in the Elderly committee of the Alliance for Clinical Trials in Oncology; serve on the editorial board of the *Journal of Geriatric Oncology*; and am a former member of the External Advisory Board of the University of Iowa Cancer Center, Governing Board Cancer, and the Kidney International Network. I received the ASCO BJ Kennedy Award for Scientific Excellence in Geriatric Oncology in 2014, am currently serving as the Immediate Past President of the International Society of Geriatric Oncology, and was the Scientific Chair of the 2017 Annual Meeting of SIOG, which was held in Warsaw in November 2017.

Faculty Vail Workshop: 2004-2005, 2007-2009, 2015-2017, 2019
Faculty MCCR Zeist: 2019
Research areas: Geriatric oncology, gynecologic oncology

A. Craig Lockhart, MD
University of Miami-Sylvester Comprehensive Cancer Center

Dr. Lockhart is a Professor of Medicine and the Division Chief for the Division of Medical Oncology at the University of Miami–Sylvester Comprehensive Cancer Center. His primary academic mission centers on early clinical drug development in oncology with a focus on GI cancers.

Dr. Lockhart earned his medical degree at the University of Texas Southwestern Medical School and did his residency in Internal Medicine at Washington University in St. Louis. He completed fellowship training in Hematology and Oncology as well as a master's degree in clinical research at Duke University. After completing his training at Duke, Dr. Lockhart was an assistant Professor of Medicine in the Division of Hematology/Oncology at Vanderbilt University. More recently, he served as the director of the Developmental Therapeutics program for the Siteman Cancer Center at Washington University from 2008-17.

Dr. Lockhart has led gastroesophageal cancer cooperative group and multi-institutional clinical trials and was a member of the NCCN guidelines committee for the management of esophageal and gastric cancers. He was also a member of the Oncology Subspecialty Board for the ABIM.

He has served as the chair of the Career Development Subcommittee for the American Society of Clinical Oncology (ASCO), where he organized the ASCO Annual Meeting sessions intended for junior members and trainees. Dr. Lockhart also served on the AACR Educational Committee. Over the last 16 years he has formally mentored 14 trainees and junior faculty. Eight of the mentees currently hold academic positions.

Specialty areas/Workshop history:

- Phase I and II clinical trials
- Gastroesophageal cancers
- Incorporating correlative studies
- Third year on Vail Workshop faculty

Wendy B. London, PhD
Harvard Medical School

Dr. London is an Associate Professor of Pediatrics, Harvard Medical School, and the Director of Biostatistics and the Director of the Clinical and Translational Investigation Program (CTIP) in the Division of Pediatric Hematology/Oncology at Dana-Farber Cancer Institute and Boston Children's Hospital. She is the Director of the Survey and Data Management Core, Dana-Farber/Harvard Cancer Center. Dr. London was awarded her PhD in Biostatistics from Virginia Commonwealth University. She has over 20 years of experience in design, conduct, analysis, and reporting of clinical trials and biologic studies in pediatric cancer. Dr. London serves as a member of the Children's Oncology Group (COG) Neuroblastoma Steering Committee and was Lead Statistician for the COG Neuroblastoma Committee (1998-2014). She collaborated/designed/conducted phase III trials in high-risk neuroblastoma that set a new standard of care: FDA approval of the immunotherapy, dinutuximab, and superiority of two autologous stem cell transplants. Dr. London was instrumental in developing the COG Neuroblastoma Virtual Tumor Bank of specimen, biology, and outcome data, and developed automated systems for assigning risk group (treatment intensity). Dr. London has served as a permanent member of the NIH/NCI Clinical Oncology Study Section (2006-10), on NIH/NCI Subcommittee H in review of the cooperative groups, and on the American Society of Clinical Oncology (ASCO) program committee (2014-16). She is a member of the *Journal of Clinical Oncology* editorial board and a faculty member of the AACR/ASCO Methods in Clinical Cancer Research Workshop (Vail, CO) (2011-2018). Dr. London chairs the Statistics Committee of the International Neuroblastoma Risk Groups (INRG) task force, where she collaborated to develop a global system for pretreatment risk stratification.

Specialty areas/research focus:

- Neuroblastoma
- Clinical trial design: phase I and randomized phase II and III trials
- Identification and application of prognostic factors
- Informatics: data warehouse design and development
- Pediatric solid tumors

Andrew M. Lowy, MD
University of San Diego, Moores Cancer Center

Andrew M. Lowy, MD, is Professor of Surgery, Chief of the Division of Surgical Oncology, and Clinical Director for Cancer Surgery at UC San Diego, Moores Cancer Center. Dr. Lowy attended Johns Hopkins University and Cornell University Medical College. He did his residency training at Cornell/New York Hospital and Memorial Sloan Kettering Cancer Center and his surgical oncology training at the MD Anderson Cancer Center. Dr. Lowy's clinical practice and research focus on pancreatic cancer. He runs a basic research laboratory that has been continuously funded by the NIH since 1999 and is also currently funded by Stand Up To Cancer and the California Institute for Regenerative Medicine. Dr. Lowy's laboratory codeveloped the first genetically engineered mouse model of pancreatic cancer and currently focuses on the identification and testing of novel therapeutic targets in pancreatic cancer. He served as cochair for the National Cancer Institute's Pancreatic Cancer Task Force from 2007-2016 and has served as chair since 2016. He also serves on the board of the National Pancreas Foundation and is chair of the Pancreatic Cancer Action Network's scientific and medical advisory board.

Research interests:

- Pancreatic cancer/study of MST1R kinase as a therapeutic target
- Pancreatic cancer/targeting pancreatic cancer stem cells
- Pancreatic cancer/new target discovery
- Pancreatic cancer/development of a neoadjuvant phase II platform study to investigate novel therapeutics in potentially resectable disease
- Appendiceal cancer/development of preclinical models to facilitate new target discovery and novel therapeutic strategies

Stuart Lutzker, MD, PhD
Genentech

Stuart Lutzker is the Vice President of Oncology Early Clinical Development at Genentech, where he is accountable for the clinical development of all oncology drugs prior to their entry into registrational studies. He joined Genentech in 2004 and assumed leadership of the Oncology Early Clinical Development Group in 2008. He has evaluated >100 drugs in first-in-human studies and has overseen the early clinical development of seven FDA-approved drugs. He has represented Genentech on a number of outside panels evaluating oncology drug development, including those convened by the Friends of Cancer Research and Institute of Medicine, and has been a member of various industry task forces.

Dr. Lutzker earned his BA from Columbia University and his MD-PhD from the College of Physicians and Surgeons at Columbia. He completed his Internal Medicine and Medical Oncology training at Yale-New Haven Hospital and a Research Post-Doctoral Fellowship in the Department of Molecular Biology at Princeton University. He previously held dual appointments in the Departments of Internal Medicine and Biochemistry at UMDNJ (now Rutgers) Cancer Institute of New Jersey prior to joining Genentech.

Specialty preferences: Lung cancer, phase I and II studies, combination studies, drug-diagnostic codevelopment, pharmacodynamic markers

Josh Mailman
NorCal CarciNET Community

Josh Mailman was diagnosed with pancreatic neuroendocrine tumor (PNET) in 2007. Josh is an internationally recognized advocate for NET patients as well as an advocate for integrative oncology and nuclear medicine and molecular imaging.

He is the inaugural chair of the Society of Nuclear Medicine and Molecular Imaging's (SNMMI) Patient Advocacy Advisory Board, a member of The Education and Research Foundation for Nuclear Medicine and Molecular Imaging (ERF) Board, acting COO of the World Association of Radiopharmaceutical and Molecular Therapy (WARMTH), and president of NorCal CarciNET Community, one of the largest NET patient communities in the United States. In addition, he is a member of National Cancer Institute's GI Steering Committee after being a member of the NCI Task Force on Neuroendocrine Tumors for six years. Josh is also a member of the Board of Directors and Executive Committee of the Neuroendocrine Tumor Research Foundation (NETRF). He sits as the single patient member of NETF's Scientific Advisory Committee, which reviews research applications for private funding by this 501c3 foundation.

In 2015, Josh was honored with the Warner Advocacy Award, given annually by Novartis Oncology Patient Advocacy and The NET Alliance. The award recognizes an individual for leadership and advocacy for neuroendocrine patients. In the same year, Josh was given the SNMMI's President's Award for his work on behalf of patients in the nuclear medicine field. Josh is a former executive board member of the Society for Integrative Oncology (SIO) and was named SIO Patient Advocate of Year in 2010.

Josh lives in Oakland, California with his wife Juliette and their eleven-year-old son.

Specialty preferences: Neuroendocrine tumors, Cancers of the GI Tract, Theranostics, Rare diseases, Access and availability (worldwide), Support Communities

Pamela R. Moffitt
Independent Advocate

Experience with specific disease:
In October 2003 I was diagnosed with an 8-cm mass in the upper left lobe of my lung, stage III non-small cell lung cancer (squamous cell), and my world dissolved. The only thing I knew about cancer was that the treatment was equivalent to rat poison and you died. Not a future anyone would want to be facing. It meant no 40th wedding anniversary, why buy presents I'd be dead by Christmas, not being there when my youngest grandson started kindergarten, not being there!

On the first day of chemotherapy of carboplatin paxitaxol my oldest daughter, an RN, said, "Today we start killing cancer cells." That was the turning point, I knew I could fight this disease. It wasn't easy but by the third treatment the doctor had given me the tools to ease the long bone pain, the nausea, the vomiting, and the crying that never seemed to stop. Six weeks later on January 4, 2004 I had thoracic surgery where my upper left lobe was removed, but during the surgery the surgeon found a 0.03 cm on the lower left lobe; the surgeon told my family that normal procedure was to sew me up. But he chose to remove the mass even though I was now a stage IV. Unknown to me the surgeon had told my family (including my 13-yr.-old granddaughter) that I had a 20 to 30% chance to live 2 years.

After 6 weeks of healing where I had breakthrough pain that required additional medications, I started chemoradiation therapy. After having mapping (commonly called tattooing) done that guided the location of the beam I had 33 rounds of radiation in conjunction with three more rounds of carboplatin paxitaxol. I had to have a port put in because I also had to have Ethyl by IV every time I had radiation. I jokingly say I have a tattoo that doesn't make a picture and endured the most expensive doctor-ordered sunburn. There were weeks where I could hardly swallow; my neck hurt so bad I would wrap moist hand towels around it to help ease the pain. I was tired all the time, especially the weeks I had the chemo treatment. One of my best friends is a professional cook; she drove me to my treatments, picked up groceries, and prepared our evening meal so I would eat. It is essential to have a support team of both friends and family.

It has been over 15 years and unknown to the surgeon at the time, he got it all. In April of 2012 my oncologist told me they had been watching a GGO for over 2 years (I was unaware they were using "watchful waiting") and needed a PET to determine if it was time to take action. I was offered a clinical trial and believe they should be offered if available to everyone that qualifies. Unfortunately, some doctors won't offer clinical trial information to their patients, especially if they consider them elderly. Although I was offered a clinical trial, I declined and on June 6th I had VATS to remove a 2-cm mass (this time adenocarcinoma) on my upper right lung. It was a new primary; thus I am still cancer free on the original lung cancer (having not had treatment on that site since my last chemo in May 2004). We have been watching a nodule for 4 years that is shrinking and I can do shrink.

Advocacy experience in specific disease area:
I have attended support group meetings but felt like the lone stranger; there are no other lung cancer survivors attending. To me we are survivors the minute we are diagnosed because unknown to anyone

we have been living with and surviving the disease for some time. But for some reason, probably the stigma tied to lung cancer, people with lung cancer are ashamed to admit they have the disease. As a society we have shunned them, we blame them and feel they deserve what they get. Thankfully, little by little the public opinion has changed and someday everyone will feel that no one deserves cancer regardless of the type.

Because I made homemade business cards and had left one with my oncologist, I was contacted by one of the chairpersons with NCCTG (North Central Cancer Treatment Group), one of the Coalition of Cancer Cooperative Groups (CCCG). I was asked to join and attended the Scientific Cancer Leadership meeting. What a learning experience that was, not just for me but for the doctors, researchers and pharmacy representatives. They admitted they had never asked the patient for their opinion; that day they found out that we had a voice and it was going to be used.

As a NCCTG advocate for Lung Cancer I was on the Patient Advocate Committee, served on the Lung Cancer Steering Committee, asked to serve on the Surgery Committee, and invited to attend the Surgery Steering Committee. I have done peer reviews on many lung cancer protocols and gained an insight into the scientific workings of the researchers' minds while noting that the patients' needs are often not included in the protocol.

I was accepted as a Lung Cancer Patient Advocate for ACOSOG (American College of Surgeons Oncology Group) another CCCG group and still served on NCCTG committees. I served as a member on the Thoracic Committee where proposed clinical trials are discussed along with trials that are being accrued. It is very gratifying to see your name as the Patient Advocate on trials that you have reviewed. Recently this comment from the Clinical Trials Manager really meant a lot to me: "Thank you Pam. Your input is what I really need!"

I am also an alumni member of RAN (Research Advocacy Network), a member of: LCCH, National Lung Cancer Partnership, LCA, CanSAR, NCCS, HOG (Hosier Oncology Group), C3, Colon Cancer Solutions, Lung Cancer Advocacy Summit Alumni Forum and a Lung Cancer Google Group. I receive daily lung cancer alerts and e-mail from OncologySTAT News, OncologySTAT InfoBLAST, NCI Cancer Bulletin, ASCO Express, CancerConnect, American Lung Association, Imedex E-Learning Center, National Comprehensive Cancer Network (NCCN), U.S. Food & Drug Administration (FDA) Daily Digest Bulletin, Clinical Care Options, Caring Ambassadors Lung Cancer E-News, Legacy for Health, U.S. Dept. of Health & Human Services, OncoFacts, NCI-Nealon Digest, NCI Office of Advocacy Relations

List serves I am on are:
Alliance-PA, Team Inspire, ACOR, PAIR

Describe your ability to represent patients and communicate their perspective:
I have presented at NCCTG meetings on attending the Scientific Leadership Conference and on Lung Cancer. I spoke at the Roger Maris Center on my journey through lung cancer and at the Women's Clinic on the relationship between radon and lung cancer. I volunteered at the local cancer center on chemo days, sitting with patients comforting them and encouraging them to ask questions about their disease and possible treatment options including clinical trials. Having been a patient, I have a better understanding of a diagnosis of lung cancer and what it can do to your mind, life, and family.

I sat on a one-day panel for the NCCN where I was able to give the patient/survivor aspect of the lung cancer journey.

I presented to the Respiratory Committee at the November 2017 Alliance meeting in Chicago, where I asked the doctors and researcher to consider using patient advocates and patient research advocates when their concepts are first beginning. If the experience of advocates were to be utilized early on, it would add a human face and sense of urgency to cancer research, ensure patient focus, provide a diverse perspective, stimulate discussion, and expand public understanding of science.

Describe your knowledge and skills specific to the disease area:
While the main focus of the Alliance is advocating for clinical trials, my greater interest lies in doing reviews on clinical trial protocols, informed consents, concepts in lung cancer, and patient information materials. The patient voice is best heard if we are included at the beginning of the process, not after the fact.

I was just notified that I have been chosen to serve on the Alliance Member Services Enhancement Task Force. I am serving as the Alliance Patient Advocate on one arm of the Alchemist Trial and have reviewed lung cancer patient pamphlets for ASCO, RAN, and ACOSOG. I have done peer reviews of protocols for NCCTG, ASCOSOG, HOG, DoD, CDMRP, and FDA. I also serve as a Patient Consultant to the FDA on lung cancer drugs. Being able to bring the perspective of the patient to the table is very rewarding while also educating the researchers on the human aspects in their trials.

I am an alumnus of RAN where I had training in advocacy research. I attended and recommended 15 lung cancer survivors/advocates when ACOSOG held a one-day lung cancer clinical trial training. I attended the CCCG Patient Advocate Training for several years. Attending the AACR Survivor-Scientist in Philadelphia helped strengthen my research knowledge.

When the NCI Office of Liaison Activities held the "Listening and Learning Together: Building a Bridge of Trust" conference I was able to attend. I attended the twice-yearly NCCTG meetings as well as the summer symposiums, the CCCG annual meetings, ACOSOG meetings, several of the NLCP annual and alumni meetings, and Prevent Cancer meetings. Because of the reorganization of the cooperative groups I now am on the Patient Advocate Committee, a lung cancer representative to the Respiratory Committee, a member on the Thoracic Surgeons Group and the Cancer and the Elderly group for the ALLIANCE (formerly NCCTG, CALGB and ACOSOG), and have attended ASCO for four years.

I have been fortunate to have been able to be a consumer reviewer for the DoD Lung Cancer concepts since its inception, reviewing an average of 13 concepts online every year. I reviewed concepts online and served on the live panel (reviewing more concepts) in November 2012, 2015, and 2016. It is always exciting to think that one of those concepts might be the breakthrough that the lung cancer community has been awaiting.

I am a faculty member of the AACR/ASCO Methods in Clinical Cancer Research for lung cancer. I attend the workshop in Vail, CO in July and will serve for 1 more year.

Alternate disease experience:
My husband is a 9-year survivor of prostate cancer and had IMRT radiation treatments. Being able to help him understand what he was feeling and the effects of treatment gave both of us strength throughout his cancer journey.

In November of 2012 I sat as the Patient Representative on a NDAC panel for overactive bladder.

In March of 2007 I suffered a serve bout of shingles that landed me in the hospital for 5 days. I still have residual pain from the disease along with nerve damage and take medication daily. It is especially important for everyone with a compromised immune system to get the shingles vaccine if possible.

Work experience:
Most of my working life was spent working with numbers as a bookkeeper, tax preparer, assistant manager, telephone and information operator, and service writer. I served as editor of the monthly newsletter of Vista Hermosa, a 103-unit 55+ senior community, plus serving as Vice President and then President of that HOA.

Education and certifications:
CER Training
Human Research Participants 11/12/13 Certificate #1325269
NCCTG (Mayo Clinic) Patient Advocate Training, Clinical Trial Training
CCCG Patient Advocate Leadership Training, CCCG Clinical Trial Modules
FDA SGE Training courses for the past 6 years
RAN (Research Advocacy Network) Training Courses:

- Genomics in Cancer
- Pathology and Tissue Research
- Biomarkers in Cancer
- Statistics for Advocates
- Clinical Trial Design
- Tumor Tissue

I attended K -12 grade in my home town of Sioux Rapids, IA. At the age of 40 I started college and earned my Certificate for Office and Secretarial Assistant. I still have one 4-credit class to take for my AA degree; interestingly, it is a science course. Working and cancer have interrupted my concluding the study course.

Ruth O'Regan, MD
University of Wisconsin

Dr. O'Regan is the Division Head of Hematology and Oncology in the Department of Medicine and an internationally recognized breast cancer clinical researcher. She oversees all aspects of UWCCC clinical research including chairing a committee, which reviews and sets policy for UWCCC clinical research. She has been instrumental in our clinical research reorganization, increasing opportunities for junior investigators via the Big Ten Cancer Research Consortium (she serves as Vice Chair of the Steering Committee) and our successful National Comprehensive Cancer Network (NCCN) application and membership.

Dr. O'Regan previously was the Louisa and Rand Glenn Family Chair in Breast Cancer Research at Emory University, in addition to medical director at Glenn Family Breast Center of Emory University, and director of the Breast Cancer Translational Research Program at the Winship Cancer Institute. Her research program focuses on identifying mechanisms of resistance to breast cancer therapies and the development of innovative breast cancer therapies. She has active funding and portfolio as PI of several breast specific clinical trials. She served as a Co-PI of NCI funded U01CA189283 with City of Hope.

Byung Park, PhD
Knight Cancer Institute

Byung Park is an Associate Professor of Biostatistics in the OHSU-PSU School of Public Health, Associate Director of Biostatistics Shared Resource (BSR) with the Knight Cancer Institute (KCI), and Associate Director of Biostatistics and Bioinformatics Core (BBC) at the Oregon National Primate Research Center. He has a strong interest in the design and analysis of oncology clinical trials and immunology. He has a longstanding collaboration with investigators from KCI and Oregon National Primate Research Center (ONPRC), since he joined the Oregon Health & Science University as a collaborative biostatistician (2002-present). He served as local organizer for the 3rd Pacific Rim Cancer Biostatistics Conference (2019) in Portland, OR, and the 2019 WNAR/IMS/JR annual meeting. He currently serves as a reviewer for the Clinical Research Review Committee and Data Safety Monitoring Committee, KCI.

Specialty areas/research focus, history with this Workshop:

- Collaborative biostatistician in the field of cancer clinical trials: designs of earlier phases of oncology clinical trials
- Collaborative biostatistician in the field of immunology (nonhuman primate studies)

- Collaborative biostatistician in the field of high-dimensional data (omics)
- Protocol review: Served 10+ years as a member of Clinical Research Review Committee and Data Safety Monitoring Committee, Knight Cancer Institute
- Student participant in AACR Cancer Biostatistics Workshop: Developing Target Agents (2008), Sonoma, CA
- Faculty member: ASCO/AACR Workshop on Methods in Clinical Cancer Research (2018), Vail, CO

Jyoti D. Patel, MD
University of Chicago

Dr. Jyoti D. Patel is Directory of Thoracic Oncology and Professor of Medicine at the University of Chicago. Dr. Patel specializes in the treatment of patients with lung cancer and other thoracic cancers. She is the Director of Thoracic Oncology at the University of Chicago and oversees lung cancer clinical and research activities. She has authored numerous publications and served as the principal investigator of multiple clinical trials. She has served on national and international cancer committees including IASLC, ASCO, the Alliance for Clinical Trials in Oncology, National Comprehensive Cancer Network, Hoosier Oncology Group, and the Eastern Cooperative Oncology Group. In addition, she is the director of the Clinical Trials Office of the University of Chicago Comprehensive Cancer Center.

Clinical interests: Lung cancer, thymic tumors

Susan Perkins, MD
National Cancer Institute

Dr. Perkins is Acting Chief of the Cancer Training Branch of the Center for Cancer Training at the National Cancer Institute. She received her BS in biochemistry from North Carolina State University and her doctorate in physiology from the University of Virginia, with further postdoctoral training in neuroendocrine physiology during fellowships at Stanford University and the Johns Hopkins University. She was recruited to NCI in 1990, first as a Senior Staff Fellow and then as an Investigator in what is now the NCI Center for Cancer Research (CCR). Her research interests focused on the development of animal models to study cancer preventive strategies and interactions among nutritional factors, hormones, and genetic susceptibility to cancer. Subsequently, she was concurrently Associate Director of the NCI Cancer Prevention Fellowship Program and a member of the NCI CCR Laboratory of Biosystems and Cancer and then a Research Assistant Professor in the Department of Nutritional Sciences at the University of Texas at Austin, before returning to NCI as a Program Director in the Cancer Training Branch in 2010. Her grants portfolio includes fellowships, individual career development awards, and T32 institutional training grants.

Jane Perlmutter, PhD
Independent Advocate

Jane is a long-term cancer survivor and active advocate. While her advocacy is largely rooted in her own experiences, it is also informed by her formal training in cognitive psychology and experimental methods (PhD), computer and information science (MS) and business (MBA), as well as her career experiences which included many years in academia, not-for-profit R&D, corporate senior management, and independent consulting. Much of her advocacy has focused on clinical trials—ensuring that the patient voice is considered in selection of research questions, design of trial protocols that are sensitive to patient issues, and encouraging innovation to increase the speed of developing new treatments. She is especially interested in innovative trial designs that can speed new treatments to patients who need them and serves on the Steering Committees and lead advocate on the I-SPY 2 and TAPUR trials, two groundbreaking trials. She has been an advocate member of NCI's Breast Cancer Steering Committee,

as well as CALGB Breast Committee and the Translational Breast Cancer Consortium (TBCRC). She is currently on NCI's Cancer Imaging Steering Committee and the Alliance Cooperative Group's DSMB.

More recently, Jane has been involved in health advocacy beyond cancer. She has been involved with the Clinical Trials Transformation Initiative (CTTI), Friends of Cancer Research (FOCR), the Reagan-Udall Foundation, the Multi-Regional Clinical Trials Center (MRCT), and has been on a number of National Cancer Institute (NCI) and National Academy of Science (NAS) committees. She is past chair of the Patient Centered Outcomes Research Institute's (PCORI) Patient Engagement Advisory Panel and a current member of their Clinical Trials Advisory Committee, has developed and delivered a variety of advocacy training, has been a faculty member at the Vail Methods in Clinical Research Workshop, and is often asked to present the patient/advocate perspective at professional meetings.

Laurel J. Pracht, BS
Research Patient Advocate

Laurel is a 19-year late-stage epithelial ovarian cancer survivor in remission since early 2004. Her background includes dual Bachelor of Science degrees from the University of Nebraska as well as broker-owner of Cascade Realty in the mountains of Colorado. Her advocacy began when her PET scan was not a covered procedure; she worked closely with a group of nuclear medicine physicians at Washington University whose work resulted in the first collaboration between Medicare and the private imaging community, the National Oncologic PET Registry (NOPR). From May 2006 to September 2008 over 100,000 beneficiary scans were covered by Medicare. The NOPR is an example of coverage with evidence development (CED). A National Coverage Decision (NCD) was issued in January 2009. She is a Patient (advocate) Representative serving a second term with the NCI Symptom Management and Health-related Quality of Life Steering Committee and has been an active member of the Gynecologic Oncology Group (GOG), now NRG Oncology, a cooperative group. She is a member of the Cancer Prevention and Control (CPC) committee, the NCORP Cancer Care Delivery Research (CCDR) committee, and works closely with the GOG-225 clinical trial within the CPC. Her advocacy has expanded to represent the Medicare beneficiary voice with the Beneficiary and Family Advisory Committee, within the QIN-QIO network with special interest in the financial burden patients/beneficiaries often incur as a result of a cancer diagnosis and treatment. She is a past Patient-Centered Research Institute (PCORI) Patient Engagement Advisory Panel appointee and is a PCORI Ambassador.

Specialty areas/research patient advocate:

- Underserved, rural, minority patient access to care and clinical trials
- Patient-clinician shared decision-making materials
- Symptom management and quality of life as seen through the patient's lenses
- Concept reviews, NCI SXQOL Steering Committee primary and secondary priorities

Mary Redman, PhD
Fred Hutchinson Cancer Research Center

Dr. Mary Redman is an Associate Member of the Clinical Research Division of Fred Hutchinson Cancer Research Center in Seattle, Washington. She is the Lead Statistician of the Lung Cancer Committee Southwest Oncology Group and Lead Statistician of the Lung Map Trial. She received her PhD in Biostatistics from the University of Washington in 2004. Dr. Redman is interested in statistical methodology for the estimation of causal effects from observational and experimental data. In particular, she is interested in approaches to estimate the effects of time-varying treatments and/or exposures and complex systems. Dr. Redman is also a statistician with the Southwest Oncology Group statistical center. She is a statistician for phase II, phase III, and ancillary studies for lung cancers
in the Southwest Oncology Group and is also involved in prevention trials in the group.

Specialty preference:

- Clinical research division

Meredith M. Regan, ScD
Dana-Farber Cancer Institute

Meredith M. Regan, ScD, is Associate Professor of Medicine, Department of Biostatistics & Computational Biology, Dana-Farber Cancer Institute and Harvard Medical School. She earned her doctorate in biostatistics at the Harvard School of Public Health. Dr. Regan's research focuses on clinical and translational research in breast and genitourinary cancers. She is Group Statistician and Director of the Statistics and Data Management Center for the International Breast Cancer Study Group, an international cooperative clinical trials group, and is a member of the NCI Breast Cancer Steering Committee and the Early Breast Cancer Trialists' Collaborative Group steering committee. Dr. Regan also codirects the Biostatistics & Computational Biology Cores for the Dana-Farber/Harvard Cancer Center Prostate Cancer SPORE and Breast Cancer SPORE. This is her eleventh year as faculty.

Specialty preferences: Biostatistics, particularly applied in breast and genitourinary cancers

Jacalyn Rosenblatt, MD
Harvard Medical School

Dr. Jacalyn Rosenblatt received her MD at McGill University School of Medicine in 1997. She completed her internal medicine residency training at McGill University Health Center and a fellowship in Hematology/Oncology at Beth Israel Deaconess Medical Center. Dr. Rosenblatt joined the attending staff of Hematology/Oncology at Beth Israel Deaconess Medical Center in 2003 and is an Associate Professor of Medicine at Harvard Medical School. Dr. Rosenblatt`s research has focused on a translational research program for immunotherapy for hematologic malignancies. She leads the multiple myeloma program at BIDMC, is codirector of the cancer vaccine and cellular immunotherapy program, and is medical director of the Cellular Immunotherapy Cell Manipulation Facility at BIDMC.

Research focus:

- Immunotherapy for hematologic malignancies
- Multiple myeloma
- Acute leukemia
- Cancer vaccines
- CAR T cells

Kurt A. Schalper, MD, PhD
Yale University

Dr. Schalper trained as a cell/molecular biologist and surgical pathologist. His professional experience includes molecular diagnostics and measurement of tissue biomarkers for companion diagnostics in cancer. Currently he is Assistant Professor of Pathology at Yale University and director of the Translational Immuno-oncology Laboratory at the Yale Cancer Center. His group aims to produce and support high-quality translational research in cancer research and immuno-oncology through standardized analyses of biomarkers for clinical trials and cross-integration with other Yale resources. These efforts could open new opportunities for biomarker discovery, identification of targets, and patient selection for novel anticancer therapies. This is his third year as a faculty member of the Workshop, and he has participated in numerous projects supporting the biomarker/biospecimen plan and analysis strategy.

Specialty areas:

- Pathology
- Biomarkers
- Immuno-oncology
- Clinical trials
- Lung cancer

Manish Shah, MD
Weill Cornell Medicine

Manish Shah, the Bartlett Family Associate Professor of Gastrointestinal Oncology at Weill Cornell Medicine, is recognized as an excellent clinical and translational investigator focusing on drug development and advancing the care of gastrointestinal malignancies. He received a BES in Biomedical Engineering from Johns Hopkins University, an MD from the Harvard/MIT Health Sciences and Training program, and completed his training in Oncology at Memorial Sloan Kettering/Weill Cornell Medicine, where he was chief fellow. Presently, his academic titles include Chief, Solid Tumor Oncology Service; Director, Gastrointestinal Oncology Program at Weill Cornell Medicine; and Co-Director, Center for Advanced Digestive Care, New York Presbyterian Hospital. Dr. Shah was a former student at the Vail Workshop as a fellow at Memorial Sloan Kettering.

Dr. Shah's current research interests include:

- Early drug development in gastrointestinal malignancies (phase I and II studies)
- Developing targeted therapies in gastric and esophageal cancers, particularly with a focus on immunotherapy and immunotherapy combinations
- Understanding the basis for resistance to taxanes in upper GI cancers
- Understanding the gastric and esophageal microbiome and how that may affect regional immunity
- Defining disease subtypes of gastrointestinal malignancies to improve patient management and drug development

Franklin O. Smith, III, MD
University of Cincinnati

Franklin O. Smith, III, MD, is Vice President at Medpace and Professor of Medicine and Pediatrics at the University of Cincinnati College of Medicine. Prior to joining Medpace in 2014, Dr. Smith served as the Clinical Director of the University of Cincinnati Cancer Institute at the University of Cincinnati, Director of the Division of Hematology/Oncology at Cincinnati Children's Hospital Medical Center, and Vice-Chair of the Children's Oncology Group. Dr. Smith received his BS from Wofford College and his MD from the University of South Carolina School of Medicine. He was a resident in pediatrics at the University of Florida College of Medicine and did fellowship training in pediatric hematology/oncology at the University of Washington and the Fred Hutchinson Cancer Research Center. Dr. Smith has clinical and research expertise in acute myeloid leukemia, cellular therapy, and marrow failure. This is his eighth year serving on the faculty of the ASCO/AACR Workshop.

Specialty preferences: Hematology/oncology; pediatric oncology; hematopoietic cell transplantation; acute myeloid leukemia; Fanconi anemia

Walter Stadler, MD
University of Chicago

Dr. Stadler is a clinical trialist focused on developing novel therapies and biomarkers, especially for genitourinary cancer. In addition to an extensive history performing trials in kidney, bladder, and prostate cancer, he also has broad experience in leading efforts supporting clinical trial infrastructure and conduct. These include renal cancer cadre leader for the Cancer and Leukemia Group B (CALGB, now Alliance), PI for a DOD-funded prostate cancer clinical trials consortium, co-PI for a Prostate Cancer SPORE, PI for the NCI-funded N01 contract for early-phase clinical trials, leader for institutional effort to coordinate multi-institutional clinical trials, and now as Dean for Clinical Research. As Deputy Director of the University Chicago Medicine Comprehensive Cancer Center (UCCCC), he is a member of the Senior Leadership Team that is responsible for developing and creating the environment and infrastructure necessary for collaboration among a diverse and dedicated team of outstanding basic, clinical, translational, and population researchers, and trainees. As Dean for Clinical Research, he is responsible for institutional policies, procedures, and infrastructure to provide education and training in clinical trial methodology to staff and faculty, assure institutional compliance, and grow clinical trial activity throughout the medical center and its network. This is his third year as a Workshop faculty member.

Research specialties:

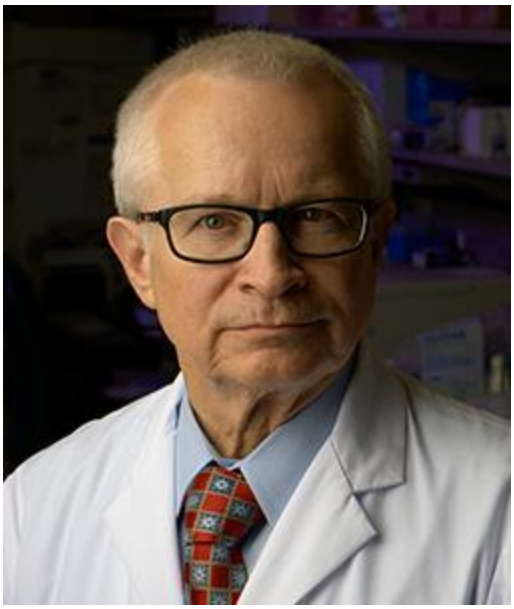
- Genitourinary cancer
- Phase I and II clinical trials
- PK and PD biomarkers
- Clinical trial infrastructure

Roger Stupp, MD
Northwestern University

Roger Stupp, MD, is the Paul C. Bucy Professor of Neurological Surgery and Professor of Medicine (Hematology/Oncology) and Neurology at Northwestern University, Chicago, IL. He is also the Associate Director for Strategic Initiatives, Robert H. Lurie Comprehensive Cancer Center, Chicago, IL; Medical Director, Northwestern Brain Tumor Institute and Chief, Division of Neuro-Oncology, Department of Neurology, Northwestern Medicine; and Immediate Past President, European Organisation for Research and Treatment of Cancer (EORTC), Brussels/Belgium. Dr. Stupp trained in internal medicine in Switzerland and in hematology/oncology at the University of Chicago. He served for over 17 years in numerous roles as a clinician and researcher at the University of Lausanne and as the Director of the Department of Oncology at the University Hospital in Zurich, Switzerland. In 2017 he was appointed to Northwestern University in Chicago. Dr. Stupp has served as a member of the Board of Directors and Executive Committee of the European Organisation for Research and Treatment of Cancer (EORTC) since 2006 (President from 2012-2017). Dr. Stupp's research focuses on early drug development, the combination of chemo- and radiotherapy, and multidisciplinary cancer management, specifically in the areas of lung cancer and brain tumors. He is best known for his contributions in landmark trials establishing temozolomide and, most recently, tumor treating fields as the standard of care for glioblastoma. This is his first year as a Workshop faculty member.

Research specialties:

- Primary and secondary brain tumors
- Multimodality therapy of lung cancer and glioma
- Clinical trials design
- Translation from the bench to the bedside



Daniel D. Von Hoff, MD, FACP, FASCO, FAACR
Translational Genomics Research Institute

Daniel D. Von Hoff, MD, FACP, FASCO, FAACR is currently Physician in Chief, Distinguished Professor at the Translational Genomics Research Institute (TGen) in Phoenix, Arizona. He also holds the Virginia G. Piper Distinguished Chair for Innovative Cancer Research at HonorHealth Clinical Research Institute and Medical Director of Research at McKesson Specialty Health and the Chief Scientific Officer for US Oncology Research specializing in phase I clinical trials. He is also Professor of Medicine, Mayo Clinic, Scottsdale, AZ.

Dr. Von Hoff's major interest is in the development of new anticancer agents, both in the clinic and in the laboratory. He and his colleagues were involved in the beginning of the development of many FDA-approved agents we now use routinely, including mitoxantrone, fludarabine, paclitaxel, docetaxel, gemcitabine, irinotecan, nelarabine, capecitabine, lapatinib, vismodegib, nab-paclitaxel, nal-IRI, and others. His clinical trial work has led to the approval of three of the four drugs approved by the FDA for treatment of patients with advanced pancreatic cancer. At present, he and his colleagues are concentrating on the development of molecularly targeted therapies, particularly for patients with advanced pancreatic cancer.

Dr. Von Hoff has published more than 675 papers, 140 book chapters, and over 1,170 abstracts. Dr. Von Hoff received the 2010 David A. Karnofsky Memorial Award from the American Society of Clinical Oncology for his outstanding contributions to cancer research leading to significant improvement in patient care.

Dr. Von Hoff was appointed to President Bush's National Cancer Advisory Board in 2004-2010. Dr. Von Hoff is the past President of the American Association for Cancer Research (the world's largest cancer research organization), a Fellow of the American College of Physicians, and a member and past board member of the American Society of Clinical Oncology. He is a founder of ILEX™ Oncology, Inc. (acquired by Genzyme after Ilex had two agents, alemtuzumab and clofarabine, approved by the FDA for patients with leukemia). Dr. Von Hoff is founder and the Editor Emeritus *of Investigational New Drugs–The Journal of New Anticancer Agents* and past Editor-in-Chief of *Molecular Cancer Therapeutics*. He is a cofounder of the AACR/ASCO Methods in Clinical Trial Cancer Research Workshop, which has graduated more than 2,000 clinical trial physicians. He is also proud to have been a mentor and teacher for multiple medical students, medical oncology fellows, graduate students, and postdoctoral fellows.

Nolan Wages, PhD
University of Virginia

Dr. Wages is an Associate Professor in the Division of Translational Research & Applied Statistics in the Department of Public Health Sciences at the University of Virginia (UVA). He is also an active member of the UVA Cancer Center Biostatistics Shared Resource. Dr. Wages received his PhD in Statistics from UVA in 2010. He is part of a national research effort to change the way early-phase clinical trials in oncology are done, not only through the pursuit of novel statistical methods but also by focusing on successful implementation of developed methods into real studies. He collaborates with cancer center members in tailoring clinical trial designs to meet contemporary research objectives in early drug development. Most of his collaborative research involves work with the Human Immune Therapy Center at UVA. Trial design methodology developed by Dr. Wages has been implemented in recently completed and currently ongoing early-phase clinical trials at UVA and other institutions. He served as a member of the NCI Investigational Drug Steering Committee Clinical Trial Design Task Force Working Group. He attended the Workshop as a participant in the biostatistician training program in 2013 and has been on the faculty since 2018.

Specialty areas:

- Phase I clinical trial design
- Early-phase drug combination studies
- Patient heterogeneity in dose-finding trials

Thomas Yankeelov, PhD
The University of Texas at Austin

Dr. Yankeelov holds an MA and MS in Applied Mathematics and Physics, respectively, from Indiana University, and a PhD in Biomedical Engineering from the State University of New York at Stony Brook. He is currently the W.A. "Tex" Moncrief Chair of Computational Oncology and Professor of Biomedical Engineering, Diagnostic Medicine, and Oncology at The University of Texas at Austin. He also serves as the Director of the Center for Computational Oncology at the Institute for Computational and Engineering Sciences. Within the Livestrong Cancer Institutes, Dr. Yankeelov is the Director of Cancer Imaging Research and program coleader for the Quantitative Oncology Research Program. The overall goal of Dr. Yankeelov's research is to improve patient care by employing advanced in vivo imaging methods for the early identification, assessment, and prediction of the response of cancer to therapy. His team develops tumor forecasting methods by employing patient-specific, quantitative imaging data to initialize and constrain predictive, multiscale biophysical models of tumor growth for optimizing therapies for the individual patient. This is accomplished by dividing his efforts into approximately equal parts mathematical modeling and development, validation, and implementation of advanced imaging in preclinical and clinical studies.

Specialty areas:

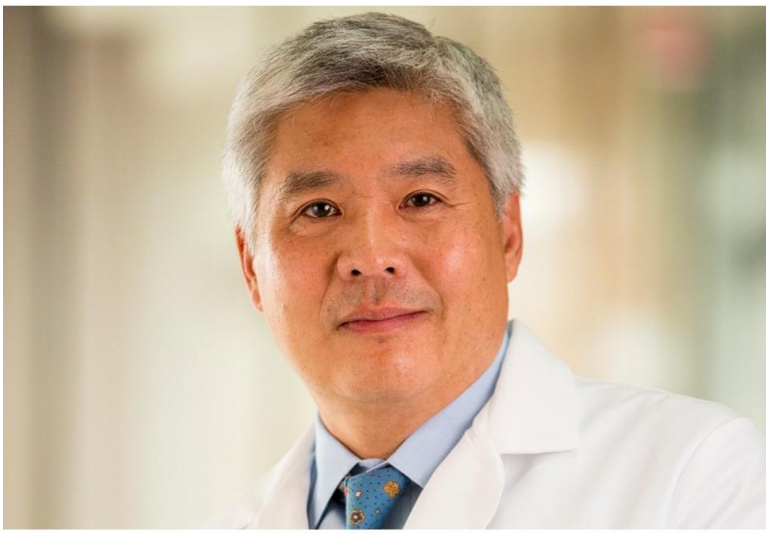
- In vivo biomedical imaging, especially magnetic resonance imaging
- Breast cancer
- Preclinical
- Imaging in clinical trials
- Mathematical and biophysical modeling of cancer

Timothy Yap, PhD
The University of Texas MD Anderson Cancer Center

Dr. Timothy Yap is a Medical Oncologist and Physician-Scientist based at the University of Texas MD Anderson Cancer Center. He is an Associate Professor in the Department for Investigational Cancer Therapeutics (Phase I Program) and the Department of Thoracic/Head and Neck Medical Oncology. He serves as Medical Director of the Institute for Applied Cancer Science and Associate Director of Translational Research in the Institute for Personalized Cancer Therapy. Prior to his current position, Dr. Yap was a Clinician Scientist at The Institute of Cancer Research (ICR), London, and Consultant Medical Oncologist at The Royal Marsden Hospital in London, United Kingdom. Dr. Yap gained his BSc degree with First Class Honours in Immunology and Infectious Diseases at Imperial College London and was awarded the Huggett Memorial Prize. His BSc laboratory research involved an immunogenetics study into the human T-cell lymphotropic virus. He subsequently obtained his medical degree from Imperial College London, before completing general medical training in Oxford. Dr. Yap undertook a Clinical Fellowship in the Phase I Drug Development Unit at the Royal Marsden Hospital, before completing a PhD in Molecular Pharmacology at the Institute of Cancer Research under a Cancer Research UK Fellowship. His PhD laboratory research focused on the preclinical and clinical development of AKT and ROCK inhibitors, and development of associated biomarkers. Dr. Yap was a former student and also faculty member of the ECCO-AACR-EORTC-ESMO Flims Clinical Trials Workshop.

Specialty areas:

- Phase I clinical trials
- Targeting DNA repair, e.g., PARP and ATR inhibitor development
- Development of predictive and pharmacodynamic biomarkers
- Development of ctDNA as a surrogate biomarker
- Lung cancers



Douglas Yee, MD
University of Minnesota

I am the Director of the Masonic Cancer Center, University of Minnesota. I am a medical oncologist with a specialty in breast cancer and a Professor in Medicine and Pharmacology. My training was at University of Chicago (MD), University of North Carolina (Internal Medicine), and the National Cancer Institute (Medical Oncology Fellowship). I held a faculty position at the University of Texas Health Science Center at San Antonio before coming to Minnesota. As cancer center director, I have oversight of clinical trial conduct and served as local PI for studies ranging from window studies, phase I through phase III prevention and treatment interventional clinical trials. My laboratory has been interested in the regulation of cancer cells by the insulin-like growth factors (IGFs) and insulin. My clinical research involves the evaluation of novel agents in breast cancer. I am chair of the Agent Selection Committee of I-SPY2 and serve on the Executive Committee of this trial designed to validate investigational therapies in the neoadjuvant treatment of breast cancer. I also serve as coordinating investigator for the phase IB trial testing xentuzumab and abemaciclib in advanced breast cancer.

Research focus:

- Breast cancer
- Signal transduction inhibitors
- Endocrine resistance
- Neoadjuvant therapy