

FDA-AACR-ASTRO Clinical Development of Drug-Radiotherapy Combinations Workshop
with support from Cancer Research UK Combinations Alliance
February 22-23, 2018 | Bethesda, MD

Workshop Cochairs

Amanda Walker, MD, U.S. Food and Drug Administration

Amanda J. Walker, MD, is the Associate Director (acting) of Radiation Oncology in the FDA's Oncology Center of Excellence and a Medical Officer in the Office of Hematology Oncology Products. In her roles at the FDA, Dr. Walker advises industry and academia with respect to oncology products, clinical trial design, and regulatory pathways to accelerate public access to novel drugs and devices. Dr. Walker graduated summa cum laude from Indiana University and then earned her medical degree from Tufts University. She completed a preliminary year in Internal Medicine at the University of Chicago, followed by her residency training in radiation oncology at The Johns Hopkins Hospital. She previously served as Adjunct Investigator in the Radiation Oncology Branch at the National Cancer Institute. In addition to her clinical experience as a board-certified radiation oncologist, Dr. Walker has an extensive background in both clinical and translational research. She currently holds positions on numerous working groups and committees and serves as the FDA scientific liaison for radiation oncology.

Marka Crittenden, MD, PhD, Earle A. Chiles Research Institute, Providence Cancer Center; The Oregon Clinic

Dr. Crittenden is a radiation oncologist and director of Translational Radiation Research at the Earle A. Chiles Research Institute at the Robert W. Franz Cancer Center in Portland Oregon. She completed her MD PhD in immunology at Mayo Medical School and pursued her residency in Radiation Oncology at OHSU where she completed a Leonard B. Holman Fellowship. She is a practicing radiation oncologist and treats patients with multiple cancers. She also runs a preclinical laboratory that explores the interaction of radiation with the immune system. She has helped develop and is the principle investigator on a number of early phase clinical trials with radiation and immunotherapy. She also serves as co-chair of the NRG Oncology Immunotherapy Committee.

Stephen M. Hahn, MD, UT MD Anderson Cancer Center

Dr. Hahn is the deputy president and chief operating officer of The University of Texas MD Anderson Cancer Center. A recognized international leader in the field of radiation oncology, he also serves as head of the Radiation Oncology division at MD Anderson and holds the Gilbert H. Fletcher Memorial Distinguished Chair.

In his role as deputy president and chief operating officer, Dr. Hahn is responsible for day-to-day operations and management of MD Anderson, ensuring excellence across all business, clinical and faculty matters. He is highly respected for his clinical expertise, collaborative nature and deep understanding of the rapidly changing health care environment. He also co-chairs the institution's Shared Governance Committee, which includes executive leaders, division heads and faculty senate representatives.

Dr. Hahn joined MD Anderson in 2015 after serving as chair of Radiation Oncology at the University of Pennsylvania's Perelman School of Medicine from 2005 to 2014. He earned his medical degree at Temple University in Philadelphia, and completed his internship and residency at the University of California, San Francisco Hospitals. He also completed a medical oncology fellowship and radiation oncology residency at the National Cancer Institute.

An active clinician who is board certified in radiation oncology, medical oncology and internal medicine, Dr. Hahn's clinical interests and expertise include both lung cancer and sarcoma. His research focuses on the molecular causes of the tumor microenvironment, particularly the study of chemical signals that go awry (known as aberrant signal transduction pathways), and the evaluation of proton therapy as a means to improve the efficiency of radiation therapy. His research has resulted in more than 200 publications in peer-reviewed journals.

Dr. Hahn is on the board of directors for the American Society for Radiation Oncology, and he serves as a trustee for the American Board of Radiology. He is a long-standing member of the American Society of Clinical Oncology, and an active member of the American Association for Cancer Research. In 2013, he was named an American Society for Radiation Oncology Fellow.

Theodore S. Lawrence, MD, PhD, *University of Michigan*

Theodore S. Lawrence, MD, PhD, FASTRO, FASCO, is the Isadore Lampe Professor and Chair of the Department of Radiation Oncology. He is Immediate Past President of the Radiation Oncology Institute and Immediate Past Chair of the Radiation Sciences and Medicine Working Group of the American Association of Cancer Research (AACR). He is a member of the National Academy of Medicine. Dr. Lawrence is an editor of the Cancer Journal, the associate editor of Seminars in Radiation Oncology, a senior editor for Cancer Research, and a scientific editor for Cancer Discovery. He has been President and Chairman of the Board of the American Society of Radiation Oncology (ASTRO) and of the Society of Chairs of Radiation Oncology Programs (SCAROP), Chair of the National Cancer Institute's Board of Scientific Councilors and a member of the Board of Scientific Advisors, and a member of the Board of Directors of the American Society of Clinical Oncology (ASCO). For his accomplishments, he has been awarded the Gold Medal of ASTRO and of the Israeli Society of Clinical Oncology, which are the highest awards conferred by those societies, an ASCO Statesman Award, and the Radiological Society of North America's (RSNA) Outstanding Researcher Award.

Dr. Lawrence's interests in the laboratory are focused on chemotherapeutic and molecularly targeted radiosensitizers. His clinical research combines these laboratory studies with conformal radiation guided by advanced imaging and blood biomarkers for the treatment of patients with gastrointestinal and central nervous system malignancies. He is the author of over 300 peer-reviewed publications, and his work has been continuously supported by the National Cancer Institute for over 25 years.

Dr. Lawrence joined the faculty of the University of Michigan in 1987, following a fellowship in medical oncology and a residency in radiation oncology at the National Cancer Institute. He received his research degree in cell biology from the Rockefeller University, followed by his medical degree from Cornell University and an internal medicine residency at Stanford University.

Phuoc T. Tran, MD, PhD, *Johns Hopkins University*

Phuoc T. Tran, MD, PhD, is an Associate Professor of Radiation Oncology and Molecular Radiation Sciences at Johns Hopkins University. He has co-appointments in the Sidney Kimmel Comprehensive Cancer Center, Medical Oncology, the Jame Buchanan Brady Urological Institute and Cellular and Molecular Medicine Program. Phuoc is a board-certified radiation oncologist and clinically specializes in treatment of genitourinary (GU) malignancies. His laboratory research funded by the NIH and DoD focuses on tumor cell epithelial plasticity programs and novel agents to enhance the local and systemic effects of radiation. He also leads an active clinical trials program that includes interventional and translational investigator-initiated studies. He is currently the PI of the largest investigator initiated clinical trial examining the next generation AR-antagonist enzalutamide as a radiosensitizer for men with biochemical failure following surgery - SALV-ENZA. He is the NRG Oncology GU Translational Science co-chair, RSNA R&E Foundation Radiation Oncology Research study section chair, ASTRO Science Council Science Workshops Subcommittee vice chair and a NCI RTB study section member.

Phuoc received his undergraduate degree at UCSD and his MD and PhD degrees at Oregon Health and Science University. He then completed radiation oncology residency and postdoctoral fellowship at Stanford. Phuoc's graduate and postdoctoral work focused on DNA repair, cancer biology, and transgenic mouse models. He subsequently joined the

@FDAOncology

@AACR

@ASTRO_org

@CR_UK



Join the conversation with #RxRTCombos18

faculty of Johns Hopkins University where he served as Clinical Director from 2015-2017 in the department of Radiation Oncology and Molecular Radiation Sciences . He has received numerous awards for his research and clinical work from the RSNA, ASTRO, the Sidney Kimmel Foundation, the American Cancer Society, Uniting Against Lung Cancer, American Lung Association, the Movember Foundation, the Prostate Cancer Foundation and was voted a Top Doctor in Baltimore Magazine. He also serves as a Senior Editor/Editorial Board member for Cancer Research and the Journal of Clinical Oncology.

Workshop Speakers and Panelists

Özlem Ataman, MD, PhD, *SOTIO*

Dr. Ataman is a clinical oncologist who has academic and research background and more than 11 years of experience in the pharmaceutical industry. She has been a member of NCRI /CTRad (The Clinical and Translational Radiotherapy Research Working Group in UK for 7 years and worked to champion radiotherapy combinations in AstraZeneca, Janssen and Eisai. She received her MD and specialist degree from Dokuz Eylul University in Izmir, Turkey and her PhD from University College London, UK. She is a passionate leader in developing combination strategies working across multiple functions within industry. Her aim is to overcome barriers and to increase number of novel agents being successfully registered in combination with radiotherapy to improve outcomes for patients with cancer.

David M. Berman, MD, PhD, *MedImmune*

David Berman, MD, PhD, is Senior Vice President and Head of the Immuno-Oncology Franchise at AstraZeneca. Prior to that, David was Head of the Medimmune Oncology Innovative Medicines. David has spent the last 12 years developing immune-oncology therapies for a variety of cancers. Prior to joining industry, David was an attending pathologist at the National Cancer Institute.

A graduate of the Massachusetts Institute of Technology, David earned his PhD in the laboratory of Dr. Alfred Gilman at the University of Texas Southwestern Graduate School and his MD from the University of Texas Southwestern Medical School. He completed his residency in anatomic pathology at the National Cancer Institute and was a pathology fellow at The Johns Hopkins Hospital.

Gideon M. Blumenthal, MD, *U.S. Food and Drug Administration*

Gideon M. Blumenthal, MD, is acting deputy office director of the Office of Hematology and Oncology Products (OHOP). Blumenthal is a medical oncologist and serves as the associate director of precision therapeutics in OHOP. He is board certified in internal medicine, medical oncology, and hematology by the American Board of Internal Medicine. He earned his undergraduate degree from Washington University in St Louis and his medical degree from University of Maryland School of Medicine. He completed an internal medicine residency at University of Maryland, followed by a hematology/oncology fellowship at the National Cancer Institute. Blumenthal previously worked as a medical officer, clinical team leader in thoracic oncology and head and neck cancer, and scientific liaison for lung cancer at FDA. He was an associate investigator on several phase 1 and phase 2 clinical trials as a fellow and then as an adjunct attending physician in the thoracic malignancy branch of the NCI. Blumenthal serves as the OHOP scientific liaison to the American Society for Clinical Oncology, is a member of the Foundation for the NIH Biomarker Consortium Cancer Steering Committee, and served on the White House Cancer Moonshot Liquid Biopsy Blood Profiling Atlas in Cancer (Blood-PAC) committee. His research has focused on investigating novel intermediate endpoints and biomarkers to better inform oncology drug and diagnostic development and clinical trial design.

Helen Bulbeck, PhD, *brainstrust*

Helen is director of *brainstrust*, a brain cancer charity with a national footprint which she founded after her daughter was diagnosed with a brain tumor and after Helen was diagnosed with head and neck cancer. Helen uses the experience of

@FDAOncology

@AACR

@ASTRO_org

@CR_UK



Join the conversation with #RxRTCombos18

being a patient, relative, member of the public and a caregiver to support 1000s of patients who have cancer. She works with cancer-related institutions, professionals and charities, to ensure that she provides the most up to date, relevant and appropriate information. This 360 degree view means that she is well placed to understand the perspectives of patients, carers and health care professionals.

Her roles in *brainstrust* and as a consumer representative with various bodies are as a disseminator of information and the provision of a network and community, so that she can provide advice on achieving effective consumer involvement and creating a voice. Helen's key drivers are the patients, their carers and healthcare professionals, with whom she interacts daily. Her ethos of 'none of us is as smart as all of us' is a core value for her.

Elemental to Helen's work is high performance coaching. This sets *brainstrust* apart. When we are no longer able to change a situation we are challenged to change ourselves. The coaching relationship enables people to face these challenges, so that they learn how to develop resilience and utilise resources to their full potential.

Helen stays up to date with relevant research, ensuring her reading is not brain centric. The skills she developed whilst studying for her PhD means that she is tenacious in spirit, but with a listening ear.

Kevin A. Camphausen, MD, *National Cancer Institute*

Dr. Camphausen received his MD from Georgetown University in 1996. He completed his internship at Georgetown in 1997 and a residency in radiation oncology at the Joint Center for Radiation Therapy at Harvard Medical School in 2001. Dr. Camphausen spent two years working in the laboratory of Dr. Judah Folkman studying the interaction of angiogenesis inhibitors and radiotherapy. He joined the National Cancer Institute in July 2001 as a tenure-track investigator. He served as the deputy branch chief beginning in April 2004 and was appointed to branch chief of the Radiation Oncology Branch in 2008. Dr. Camphausen is board certified by the American Board of Radiology.

Steven J. Chmura, MD, PhD, *University of Chicago*

Steven J. Chmura MD, PhD, is the director of Clinical and Translational Research for Radiation Oncology at the University of Chicago for over a decade. He has been actively involved in both the clinical implementation of stereotactic radiosurgery (SRS) and stereotactic body radiotherapy (SBRT) and related translational and clinical research, as well as the integration of SRS and SBRT into other systemic therapies. His clinical interests include breast cancer, limited metastatic disease, immunotherapy, and technologic improvements in the delivery of radiotherapy. Dr. Chmura is an active member of the NCI cooperative group, NRG Oncology, serving on the committee for Breast Cancer and also as the liaison to the Radiation Oncology division. These efforts have led to the first international trials through NRG Oncology examining the safety of treating breast cancer patients with 3-4 metastases as well as a Phase II/III trial examining potential improvements to progression-free survival and overall survival. Dr. Chmura's work in radio-immunology has also translated into multiple investigator-sponsored trials along with the now accruing NCI-sponsored (A091605) trial randomizing the role of SBRT combined with pembrolizumab in advanced Merkel cell carcinoma; such integration of ablative radiotherapy and immunotherapy along with advancing the search for biomarkers is currently Dr. Chmura's focus.

C. Norman Coleman, MD, *National Cancer Institute*

Dr. Coleman graduated from Yale University School of Medicine. He is board certified in internal medicine (UCSF), medical oncology (NCI) and radiation oncology (Stanford). Dr. Coleman was a tenured faculty member at the Stanford before joining Harvard Medical School in 1985 as Fuller-American Cancer Society Professor and Chairman, Joint Center for Radiation Therapy. In 1999, he returned to the NCI as director of the new Radiation Oncology Sciences Program and served as chief of the Radiation Oncology Branch from 1999 - 2004 and associate director of the Radiation Research Program in the Division of Cancer Treatment and Diagnosis, 1999 - present. Since 2004 he has also been Senior Medical Advisor in the Office of the Assistant Secretary for Preparedness and Response (ASPR), HHS. His research interests are in radiation modifiers, molecular radiation oncology and health and medical preparedness and planning for radiological and nuclear emergencies. He is a Fellow of the American Society of Radiation Oncology, American Society of Clinical Oncology,

@FDAOncology

@AACR

@ASTRO_org

@CR_UK



Join the conversation with #RxRTCombos18

American College of Radiology and American College of Physicians. Among his awards are the Gold Medal from ASTRO in 2006, the Partnership for Public Service, Samuel J. Heyman Service to America Homeland Security Medal in 2011, the Failla Medal from the Radiation Research Society in 2016 and Doctor of Science (h.c.) from the University of Vermont in 2015.

Kyle Cuneo, MD, *University of Michigan*

Kyle Cuneo, MD, received his Doctor of Medicine degree from Vanderbilt University School of Medicine in 2007 and completed an internship there in 2008. In 2008 he started his residency in Radiation Oncology at Duke University Medical Center. Dr. Cuneo has been an Assistant Professor in the Department of Radiation Oncology at the University of Michigan since 2012.

Dr. Cuneo performs basic science, translational, and clinical research at the University of Michigan. His research focuses on the development of novel therapeutic approaches and biomarker discovery in gastrointestinal cancers. He serves as the principal investigator on clinical trials in pancreatic cancer, hepatocellular carcinoma, and colorectal cancer.

Adam P. Dicker, MD, PhD, *Thomas Jefferson University Kimmel Cancer Center*

Adam Dicker, MD, PhD, is Senior Vice President, Professor and Chair of Enterprise Radiation Oncology, Sidney Kimmel Cancer Center, Sidney Kimmel School of Medicine, Thomas Jefferson University, Philadelphia PA.

Dr. Dicker's work has resulted in establishment of parameters for quality assurance in radiation oncology, robotic technologies for brachytherapy, novel therapeutic clinical trials utilizing targeted therapies and ionizing radiation, innovative preclinical models to evaluate radiation modifiers and FDA/CMS approval of a genomic signature for management of prostate cancer.

Dr. Dicker leads a University-wide effort in Digital Health, using the convergence of mobile technology, platforms, networks, and machine learning to improve the lives of patients and leads a course in Digital Health in the Medical College. His group created an Apple ResearchKit app for patient reported outcomes (PROs) for prostate cancer patients "Strength Through Insight"-NCT03197948 and are conducting innovative, collaborative research to transform digital health into a standard part of clinical care. Their research is focused on collection of PROs and remote activity monitoring for patients receiving chemo-radiation, molecular targeted therapies and immunotherapy and are expanding to the non-oncology patient population. Dr. Dicker's research supported by the Prostate Cancer Foundation is focused on radiation-immunotherapy approaches integrated with digital health technologies to improve the lives of patients.

Dr. Dicker is Chair Emeritus, Integration Panel for the Prostate Cancer Research Program-Department of Defense, Vice-Chair, Translational Science and Digital Health committees for NRG Oncology (www.nrgoncology.org), and Radiation Oncology Co-Chair, NCI Genitourinary Cancers Prostate Cancer Task Force. He is a member of the National Cancer Institute Investigational Drug Steering Committee, and National Clinical Trial Network Core Correlative Sciences Committee (CTEP).

Dr. Dicker received his BA from Columbia College, and his MD and PhD (Molecular Pharmacology) from Cornell University. He received his training in radiation oncology at Memorial Sloan-Kettering Cancer Center after a surgical internship.

Zelanna Goldberg, MD, MA, *Pfizer Oncology*

Zelanna Goldberg, MD, MA, is a Global Clinical Lead (GCL) in Pfizer Oncology. She received her medical degree from the University of Toronto, Toronto, Canada and completed her radiation oncology residency at Princess Margaret Hospital, now part of the University Health Network. She completed a fellowship at Stanford University in the lab of Dr. Martin Brown and then joined the faculty at the University of California, Davis (UCD). As an assistant and then associate professor at UCD, in addition to a radiation oncology practice and participation in cooperative group studies, she ran an independent translational oncology research lab focused on measuring the biologic impact of low-dose ionizing radiation.

@FDAOncology

@AACR

@ASTRO_org

@CR_UK



Join the conversation with #RxRTCombos18

Currently, she is a GCL focused on immuno-oncology in non-small cell lung cancer and head and neck cancer. She heads the Javelin 100 HN study evaluating the addition of avelumab to chemoradiotherapy in locally advanced squamous cell carcinoma of the head and neck as well as other registrationally focused studies.

Ester M. Hammond, PhD, *University of Oxford*

Ester Hammond is Professor of Molecular Cancer Biology and a CRUK Senior Group Leader at the CRUK/MRC Oxford Institute for Radiation Oncology. She completed her PhD at the School for Cancer Sciences, University of Birmingham then accepted a post as a postdoctoral fellow within the Molecular Oncology Group at the University of Cambridge School of Clinical Medicine before moving to the USA to join the Department of Radiation Oncology at Stanford University, first as a postdoctoral fellow then a research associate. She joined the Oxford Institute in 2007 as a CRUK junior group leader and has since been promoted to senior group leader and professor. In 2015, she was awarded the Michael Fry Research award from the Radiation Research Society. Ester's research focus is on tumour hypoxia and how this impacts the response to radiation. Specifically, she has focused on the hypoxia-induced DNA damage response and how this might reveal novel therapeutic strategies/combinations to improve radiotherapy response.

Paul M. Harari, MD, *University of Wisconsin*

Dr. Paul M. Harari is the Jack Fowler Professor and Chairman of the Department of Human Oncology at the University of Wisconsin School of Medicine and Public Health. Dr. Harari earned his BS in Biology at Tufts University (1980) and his MD at the University of Virginia (1984). He completed his Internal Medicine Internship at the University of California Davis (1985) and Radiation Oncology Residency Training at the University of Arizona (1990). His clinical and laboratory research focuses primarily on treatment advances for H&N cancer patients with emphasis on the interaction of molecular growth inhibitors combined with radiation.

Dr. Harari has served as the Principal Investigator (PI) for NIH and industry sponsored research grants including his current PI role for the Wisconsin H&N Cancer SPORE Grant. He has served as the PI or Study Co-Chair for Phase II and III national and international clinical trials that investigate new treatment regimens for H&N cancer patients. He directed the Radiation Oncology Residency Training Program at the University of Wisconsin for 10 years, from 1997-2007. He served on the ASTRO Board of Directors from 2012-2016 and currently serves in the Presidential Track 2016-2020 including the role of ASTRO President in 2017-2018. Dr. Harari has authored over 230 original research articles and book chapters on cancer research topics with particular emphasis on the evaluation and treatment of H&N cancer.

Robert Iannone, MD, *AstraZeneca*

Robert Iannone is a pediatrician and pediatric hematologist-oncologist. Robert graduated with a B.S. Summa Cum Laude from The Catholic University of America ('89) as a Cardinal Gibbons Scholar and graduated with Alpha Omega Alpha honors from Yale Medical School ('94).

Robert trained in pediatrics and pediatric-hematology-oncology at Johns Hopkins Hospital, where he also served as Chief Resident. His fellowship research project focused on bone marrow transplantation under the mentorship of Ephraim Fuchs, in the Division of Immunology and Hematopoiesis. After fellowship, Robert was appointed Assistant Professor of Pediatrics at the University of Pennsylvania and Children's Hospital of Philadelphia, where he was an NIH-funded member of the section of Bone Marrow Transplantation. During this time, Robert earned a Master's of Science in Clinical Epidemiology from the University of Pennsylvania's Center for Clinical Epidemiology and Biostatistics.

In 2004, Robert joined Merck Clinical Pharmacology as an Associate Director, and thereafter held roles with increasing responsibility: Director of Clinical Pharmacology, Senior Director and Site Head for Experimental Medicine, and Executive Director and Section Head of Oncology Clinical Development. In the latter role, Robert had leadership responsibility for the development of immune-oncology assets, including Pembrolizumab, contributing to the first approved indication in melanoma and the expansion into multiple additional tumor types. He also served as Chair of the Pediatric Development Committee since its inception.

@FDAOncology

@AACR

@ASTRO_org

@CR_UK



Join the conversation with #RxRTCombos18

In July of 2014, Robert joined AstraZeneca as Global Products Vice President, and currently serves as Senior Vice President and Head of Immuno-oncology, Global Medicines Development. In this role, Robert oversees full development of late phase immune-oncology assets, including durvalumab (Imfinzi), tremelimumab and combinations with additional early and late phase assets.

Tim M. Illidge, MD, PhD, *University of Manchester*

Dr. Illidge completed his undergraduate degree in Biochemistry (BSc, London University, before his medical degree (MB BS) from Guy's Hospital, London. He trained in clinical oncology in Southampton and tumour immunotherapy formed the basis of his PhD (University of Southampton) with antibodies and radiotherapy combinations. In 1994 he was appointed a Cancer Research UK clinical fellow and in 1997 awarded Young British Cancer researcher of the year followed by a Senior Fulbright fellowship which enabled him to work in immunology at Stanford California. In 1999 he returned to the UK as the first CRUK senior clinical fellow and became a senior lecturer at University of Southampton and subsequently a personal chair in 2003. In 2004 he was appointed Professor of Targeted Therapy and Oncology at University of Manchester and leads the translational Targeted Therapy Group, Cancer Research UK Manchester Institute. The translational research programme is based around radiotherapy and immunotherapy combinations, funded by CRUK programme grant. He chaired a UK NCRI Clinical and Translational radiotherapy group from 2010-2013 and remains on the steering committee. He has published extensively and was awarded the cancer researcher of the year by university of Manchester in 2012, and subsequently the researcher of the year for the Faculty of medical and Life sciences in 2013. He led the radiotherapy related research group of the Manchester Cancer Research Centre from 2007-2016, overseeing a large increase in research staff. He is currently Head of Division of Cancer Sciences at the University of Manchester, Manchester Academic Health Sciences Centre overseeing over 180 academic staff.

David G. Kirsch, MD, PhD, *Duke University Medical Center*

David Kirsch, MD, PhD, is the Barbara Levine University Professor at Duke in the Departments of Radiation Oncology and Pharmacology & Cancer Biology. After graduating from Duke with a BS in Biology, he completed the MD/PhD program at Johns Hopkins School of Medicine, where he performed his thesis research with Dr. Michael Kastan. After an internship in Internal Medicine, Dr. Kirsch trained in radiation oncology at Massachusetts General Hospital. He worked as a post-doc in the laboratory of Dr. Tyler Jacks at M.I.T., where he developed a genetically engineered mouse model of soft tissue sarcoma. He utilized the Jacks' lab mouse model of non-small cell lung cancer to study radiation response in vivo. In 2007 Dr. Kirsch moved to Duke, where he uses radiation therapy to care for patients with sarcomas at the Duke Cancer Center. Dr. Kirsch is the leader of the Radiation Oncology & Imaging Program in the Duke Cancer Institute and serves as Vice Chair for Basic and Translational Research in the Department of Radiation Oncology. Dr. Kirsch's laboratory utilizes sophisticated genetically engineered mouse models to study mechanisms of sarcoma and normal tissue response to radiation.

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

Paul Kluetz is the Acting Associate Director of Patient Outcomes in the Oncology Center of Excellence at the U.S. FDA. He joined FDA in 2010 focusing on genitourinary cancers. From 2014-2015, he served as Acting Deputy Director of the Office of Hematology and Oncology Products, helping to develop and support regulatory science and strategic policy initiatives.

His interests include exploring various efficacy measures in oncology trials, the use of expedited programs such as accelerated approval, and opportunities and challenges associated with quantifying patient outcomes including patient reported outcomes (PRO) data, wearable technologies, healthcare utilization and other methods to obtain data on the patient experience both in the clinical trial and "real-world" settings. He is currently creating and leading a team to develop regulatory science and policy initiatives to advance patient-focused drug development in cancer trials.

Dr. Kluetz is a board certified medical oncologist and internist. He completed a medical oncology fellowship at the National Cancer Institute (NCI) in Bethesda, MD and continues to enjoy seeing patients and teaching medical house staff as an attending physician at the Georgetown University Hospital.

@FDAOncology

@AACR

@ASTRO_org

@CR_UK



Join the conversation with #RxRTCombos18

Yaacov Richard Lawrence, MD, Sheba - Tel HaShomer Hospital; Thomas Jefferson University

Yaacov Lawrence MA, MBBS, MRCP, graduated from Cambridge University and University College Hospital, London. He is board certified in Internal Medicine and Radiation Oncology. Between 2007-2010 he was a Fellow and subsequently Attending Physician at Thomas Jefferson University, Philadelphia. In 2009 he was awarded an ASCO Young Investigator Award. Currently Dr. Lawrence leads the Gastro-intestinal program within the Department of Radiation Oncology, Sheba Medical Center and heads the Research Division within the department. He is a Senior Lecturer at Tel Aviv University. He has led numerous early-phase clinical trials, and was the lead author of the "NCI-RTOG Translational Program Strategic Guidelines for the Early-Stage Development of Radiosensitizers". He has received funding from the Israel Cancer Association, European Union FP7 program, NATO, the Rosetree's foundation, and Gateway for Cancer Research.

Quynh-Thu Le, MD, FACR, FASTRO, Stanford Cancer Institute

Quynh-Thu Le, MD, received her medical school and radiation oncology training at University of California, San Francisco. In 1997, she joined Stanford, where she holds the Katharine Dexter McCormick & Stanley Memorial Professorship and is Chair of the Radiation Oncology Department.

Her research focuses on translating laboratory findings to the clinic and vice versa in head and neck cancer (HNC), specifically in tumor hypoxia, Galectin-1, and salivary gland stem cells.

Clinically, she has led multicenter phase II and III clinical trials, testing the addition of novel drugs as radiosensitizer or radioprotector with chemoradiotherapy in HNC. She has received grant support from ASCO, ASTRO as well as R01 and R21 grants from the NIH. She was inducted into the Fellowship of the American College of Radiology (FACR), the American Society of Therapeutic Radiology and Oncology (ASTRO) and the Institute of Medicine/National Academy of Medicine (IOM/NAM). She was also honored with the Caltech Distinguished Alumni Award in 2015.

Administratively, she is the Co-Director of the Radiation Biology Program at the Stanford Cancer Institute, Chair of the NRG Head and Neck Disease Site Committee, ARS President-elect and a member of ASTRO Nominating Committee. She also serves on many other national committees and as a reviewer for several cancer related journals.

Fei-Fei Liu, MD, FRCPC, Ontario Institute for Cancer Research

Dr. Fei-Fei Liu is the Chief of the Radiation Medicine Program and Head of the Department of Radiation Oncology at the Princess Margaret Cancer Center, as well as the Professor and Chair of the Department of Radiation Oncology at the University of Toronto. Dr. Liu is also a Senior Scientist at the Princess Margaret Cancer Center Research Institute, and holds the University of Toronto/Princess Margaret Cancer Center Dr. Mariano Elia Chair in Head & Neck Cancer Oncology.

Dr. Liu's research program has been focused on investigating and developing novel molecular therapeutic strategies for human malignancies, delivered in conjunction with radiation therapy, along with investigating molecular aberrancies of several human malignancies including breast, and head/neck cancers. Dr. Liu has over 175 peer-reviewed publications on these topics, and has filed three patents. She currently holds peer-reviewed research funding from agencies including the Canadian Institutes of Health Research (CIHR) and the Canadian Cancer Society Research Institute (CCSRI). She is also the founding Director of a \$1.9M Terry Fox Foundation Research Training Initiative, entitled "Strategic Training in Transdisciplinary Radiation Science for the 21st Century (STARS21)", with the objective to train the next generation of trans-disciplinary scientists in Radiation Medicine. Recently, her laboratory has shifted its focus to unraveling the mechanisms, and identifying therapeutic strategies of radiation fibrosis and lymphedema, two important late normal tissue toxicities with significant functional morbidity.

Jessica Lowenstein, MS, IROC Houston, MD Anderson

Jessica R. Lowenstein, MS, is the Associate Director of the Imaging and Radiation Oncology Core (IROC) Houston QA Center and a Senior Medical Physicist in the Department of Radiation Physics at U. T. MD Anderson Cancer Center. She is a

@FDAOncology

@AACR

@ASTRO_org

@CR_UK



Join the conversation with #RxRTCombos18

Diplomat of the American Board of Radiology (ABR). She has over 20 years of experience performing clinical trial QA and an extensive knowledge of radiation dosimetry, radiation dosimetry quality assurance and the application of these concepts in the cooperative clinical trial setting, which she uses to assure NCI and the NCTN Groups that the radiation doses delivered to clinical trial patients is accurate with minimal uncertainty. Her research, development of national standards (AAPM task group reports) and QA center day to day activities have all been focused on minimizing dosimetry errors for clinical trial radiotherapy patients.

Melinda Merchant, MD, PhD, AstraZeneca

Melinda Merchant, MD, PhD, is a Senior Medical Science Director in the Oncology IMED and Group Director of the Boston Oncology Translational Medicines Unit. A board-certified Pediatric Hematologist & Oncologist with a PhD in Immunology, Dr. Merchant held previous physician scientist positions at the National Cancer Institute (NCI) and Memorial Sloan-Kettering Cancer Center with a focus on sarcomas and immunotherapy. Melinda's 15 years of experience as a clinician scientist includes 5 years of service on the NCI IRB and a leadership role as Clinical Director of the NCI Pediatric Oncology Branch. As PI on multiple investigator initiated trials including immunotherapy agents, adoptive cell therapies, targeted agents, and pilot studies, her expertise is quite relevant to the academic – pharma collaborative teamwork required for high quality early phase clinical trials. Since her move to AZ in 2015, Melinda has been highly active in early clinical development within the AZ portfolio at the transition from laboratory to early phase clinical trials, directing clinical development of multiple first time in human studies, and leading a growing team of physician scientists. Of particular relevance to the FDA-AACR-ASTRO Workshop is her role as medical science director for AZD1390, a CNS-penetrant ATM inhibitor. The clinical development of AZD1390 includes an early PET study in healthy volunteers to confirm CNS penetration (NCT03215381) and a study of AZD1390 administered together with radiation therapy in patients with GBM or brain metastases (NCT03423628).

Andy J. Minn, MD, Abramson Family Cancer Research Institute

Dr. Minn's research is focused on how cancers acquire treatment resistance and how resistance can be overcome. His lab has identified pattern recognition receptors (PRR) and interferon (IFN) pathways across multiple cancer types. In the context of cancer, these pathways orchestrate tumor progression, response to conventional or immunotherapies, and immunosuppression. The lab is investigating how PRR/IFN signaling is activated in cancer, both cell intrinsically and through the tumor microenvironment. These PRR/IFN pathways can be therapeutically exploited to modulate the immune system. One way is through activation of the DNA damage response. An overarching goal is to translate mechanistic findings to inform clinical trial design. Dr. Minn is an Associate Professor in the Department of Radiation Oncology and Abramson Family Cancer Research Institute at the University of Pennsylvania. He received his MD and PhD from the University of Chicago and his medical and post-doctoral training at Memorial Sloan Kettering Cancer Center.

Meredith A. Morgan, PhD, University of Michigan

Dr. Morgan is an Assistant Professor of Radiation Oncology at the University of Michigan. Her formal research training is in radiation biology, experimental therapeutics, and the DNA damage response. During her post-doctoral training in the Department of Radiation Oncology at the University of Michigan, Dr. Morgan developed CHK1 inhibitors as chemoradiation sensitizers. As faculty, Dr. Morgan continued her research efforts in these areas with the goal of developing agents which inhibit the DNA damage response to sensitize locally advanced cancers to radiation therapy. Dr. Morgan's research program prioritizes pre-clinical research with strong clinical and translational relevance. In 2014, Dr. Morgan successfully translated her pre-clinical laboratory studies to a clinical trial combining WEE1 inhibition with chemoradiation in patients with locally advanced pancreatic cancer. More recent strategies being investigated in Dr. Morgan's laboratory include novel combinations of DNA damage response inhibitors as well as the effects of DNA damage response inhibitors with radiation on innate immunity. Dr. Morgan runs an NIH-funded laboratory and trains undergraduate, medical and graduate students, as well as post-doctoral and medical fellows.

@FDAOncology

@AACR

@ASTRO_org

@CR_UK



Join the conversation with #RxRTCombos18

Todd R. Palmby, PhD, U.S. Food and Drug Administration

Dr. Palmby is a Pharmacology/Toxicology Supervisor in the Division of Hematology Oncology Toxicology leading a team supporting the Division of Oncology Products 1 of the Office of Oncology Drug Products in the Center for Drug Evaluation and Research of the United States Food and Drug Administration. Prior to joining the FDA as a Pharmacology/Toxicology Reviewer in 2008, Dr. Palmby completed a post-doctoral fellowship in the Oral and Pharyngeal Cancer Branch within the National Institute of Dental and Craniofacial Research at the National Institutes of Health. Dr. Palmby received his PhD in Pharmacology from the University of North Carolina at Chapel Hill in 2004. His research experience was focused on mechanisms of cancer biology involving GTPase and kinase networks using cell and molecular biology approaches as well as tumor, knockout, and transgenic mouse models.

During his time at FDA, he has presented at national meetings on the FDA perspective of nonclinical testing of oncology therapeutics.

Tatiana M. Prowell, MD, U.S. Food and Drug Administration

Tatiana M. Prowell, MD, is Breast Cancer Scientific Liaison in FDA's Office of Hematology & Oncology Products and Assistant Professor of Oncology in the Breast Cancer Program at the Johns Hopkins Kimmel Comprehensive Cancer Center. Dr. Prowell received her BA degree from Bard College in Languages and Literature and her MD degree from the Johns Hopkins School of Medicine with election to the Phi Beta Kappa and Alpha Omega Alpha honor societies. She subsequently completed her internal medicine residency and medical oncology fellowship at Johns Hopkins Hospital. She was the principal architect of FDA's policy on accelerated approval using pathological complete response as a novel regulatory endpoint in the neoadjuvant high-risk breast cancer setting, and was a member of the Cancer Moonshot Blue Ribbon Panel Cancer Immunology Working Group. She is a frequent public speaker and a three-time recipient of FDA's Excellence in Communication Award, as well as a Giants of Cancer Care Award finalist. A passionate medical educator and mentor, she currently serves on the faculty of the Vail Methods in Clinical Cancer Research Workshop, the Accelerating Anti-Cancer Agent Development and Validation (AAADV) Workshop, the FDA/ASCO Fellows' Day Workshop, the Society for Translational Oncology Fellows' Forum, and the Dana Farber Clinical Investigator Seminar Series, among several others. She sees patients in the Johns Hopkins Second Opinion Breast Cancer Clinic and teaches in the medical school and medical oncology fellowship training program.

Jonathan D. Schoenfeld, MD, MPhil, MPH, Dana-Farber Cancer Institute

Dr. Jonathan Schoenfeld is a radiation oncologist at the Brigham and Women / Dana-Farber Cancer Center, Assistant Professor of Radiation Oncology at Harvard Medical School and the Radiation Oncology Director of the Melanoma Disease Center at the Dana-Farber Cancer Institute. With a background in immunology and clinical trial design, Dr. Schoenfeld leads multicenter and national trials testing the combination of radiation and existing and novel immune therapies.

Andrew B. Sharabi, MD, PhD, UCSD Moores Cancer Center

Dr. Andrew Sharabi, MD, PhD, is an assistant professor and board-certified radiation oncologist at UC San Diego Moores Cancer Center. He has a PhD in Immunology from Baylor College of Medicine and completed his radiation oncology residency and research fellowship at Johns Hopkins University. While at Johns Hopkins he was awarded the prestigious John G. Rangos Medal of Honor for Creativity in Cancer Discovery and published one of the first studies combining radiation therapy with anti-PD-1 checkpoint blockade immunotherapy. He has successfully translated his findings into patients and is the Principle Investigator of two investigator initiated clinical trials combining radiation therapy with immunotherapy. In addition, Dr. Sharabi serves on the ASTRO Education Committee for Immunotherapy and is an Advisory Board Member for the San Diego Center for Precision Immunotherapy.

Dr. Sharabi's research laboratory in the Moores Cancer Center focuses on development of novel immunotherapies and strategies to combine radiation with novel targeted agents in Head and Neck Cancer. He is the recipient of a KL2 grant and co-investigator on V-Foundation and NIH R01 grants supporting his research. He is also the translational co-chair of a large Phase II study randomizing patients with locally advanced head and neck cancer to definitive chemoradiation versus

[@FDAOncology](#)

[@AACR](#)

[@ASTRO_org](#)

[@CR_UK](#)



Join the conversation with #RxRTCombos18

definitive radiation combined with anti-PD-1 immunotherapy. Research blood draws from these clinical trials are being analyzed in Dr. Sharabi's lab to identify predictors of response, mechanisms of resistance, and the next generation of treatments for Head and Neck Cancer patients.

Ricky Sharma, MD, PhD, *University College London*

Professor Ricky Sharma is Chair of Radiation Oncology at University College London and the Head of Academic Radiotherapy at the UCL Cancer Institute. He is an Honorary Consultant in Clinical Oncology at University College London Hospitals and the Royal Free Hospital, where he has a clinical practice in radiotherapy and chemotherapy. He graduated in medicine from the University of Cambridge, United Kingdom. He trained in general internal medicine, medical oncology and radiation oncology and completed a PhD on DNA damage repair. Prior to his current post, Professor Sharma was an Associate Professor and Scientific Group Leader at the University of Oxford, where he was an Honorary Consultant in Clinical Oncology. Professor Sharma is an international authority on the translation of radiobiology from the laboratory to the clinic and on the multi-modality treatment of cancer with precision therapy.

Patty Spears, *UNC Lineberger Comprehensive Cancer Center*

Ms. Spears is an 18-year breast cancer survivor and cancer research advocate. She has extensive clinical trial advocacy experience having served as an advocate on the Translational Breast Cancer Research Consortium (TBCRC) and NCI Breast Cancer Steering Committee (BCSC). She is currently serving as Chair of the Patient Advocate Committee of the Alliance for Clinical Trials in Oncology and is a member of the NCI BCSC Breast Immuno-Oncology (BIO) Task Force. She is a Komen Scholar, serves as Vice Chair on the Komen Advocates in Science Steering Committee and is an FDA Patient Representative. She also has an interest in Patient Reported Outcomes (PROs) in drug development. Ms. Spears is currently working as a scientific research manager and patient advocate at UNC Lineberger Comprehensive Cancer Center.

Daniel E. Spratt, MD, *University of Michigan*

Daniel E. Spratt, MD, obtained his medical degree with AOA from Vanderbilt Medical School, and completed his radiation oncology residency and research fellowship at Memorial Sloan Kettering Cancer Center. Dr. Spratt is the Chief of the Genitourinary Program and Vice Chair of Clinical Research within the Department of Radiation Oncology at the University of Michigan. He also co-Chairs the Genitourinary Division's Clinical Research efforts across the Cancer Center. Dr. Spratt's primary disease focus is prostate cancer and his research focus spans translational bench research to early phase clinical trials. He has been the recipient of multiple grants and awards from the Department of Defense, Prostate SPORE, RSNA, ASTRO, and the Prostate Cancer Foundation. Dr. Spratt is an expert in biomarker development and has helped generate multiple prognostic and predictive gene expression classifiers, and has published over 100 papers. Dr. Spratt's laboratory focuses on the complex interplay of DNA repair and androgen receptor signaling, and has helped establish mechanisms of radioresistance in prostate cancer. Dr. Spratt is the PI and co-PI of multiple clinical trials, including the national NRG-GU006 trial, a phase II randomized biomarker stratified trial in recurrent prostate cancer.

Andrew Wang, MD, *University of North Carolina at Chapel Hill*

Andrew Z. Wang, MD, is Associate Professor and Director of Clinical and Translational Research, Department of Radiation Oncology, UNC-Chapel Hill. He is also the co-Director of the Carolina Cancer Nanotechnology T32 training program. Dr. Wang earned his undergraduate degrees from Indiana University and medical degree from the HST program at Harvard Medical School. He completed his radiation oncology training in the Harvard Radiation Oncology Program. Following residency, Dr. Wang joined the UNC faculty in 2009. Dr. Wang's research program is focused on the clinical translation of engineering sciences, including Nanomedicine, to oncology. His research spans a wide spectrum of translational research, from preclinical research to early phase clinical trials. He also co-founded Catio Biosciences, a biotech startup that is translating a nanotechnology-based circulating tumor cell capture assay.

@FDAOncology

@AACR

@ASTRO_org

@CR_UK



Join the conversation with #RxRTCombos18

James W. Welsh, MD, UT MD Anderson Cancer Center

James Welsh is the head of the Immuno-Radiation Initiative at MD Anderson Cancer Center. He earned an undergraduate degree from UC Davis. Then, worked at Genentech in molecular oncology, before attending Dartmouth Hitchcock Medical Center. Welsh completed a residency in radiation oncology at The University of Arizona Health Sciences Center. At MD Anderson Cancer Center, he studies the synergism of immunotherapies with radiation to permanently control cancer. This work includes running many of the first in human trials of anti-CTLA-4 and anti-PD1 with radiation. The Welsh laboratory developed the first pre-clinical lung cancer tumor model of anti-PD1 resistance. This model is used to study the biological mechanisms of novel immunotherapies in combination with radiation. His goal is to develop personalized therapeutic approaches to revolutionize cancer management.

Kaye J. Williams, PhD, University of Manchester

Professor Kaye Williams is Leader of the Hypoxia and Therapeutics Group within the Manchester Pharmacy School (MPS), the University of Manchester. Kaye joined MPS in November 1996. Following back-to-back Research Associate and Research Fellow positions funded by the MRC, she gained tenure in January 2006, and was promoted to Chair in Experimental Therapeutics and Imaging in August 2012. Her research focuses on the tumour microenvironment, investigating therapeutic targets, vascular biology and molecular interactions that influence tumour response to radiotherapy. Kaye also leads pre-clinical imaging development within the Manchester Cancer Research Centre. Her work is funded through research councils (MRC, BBSRC, EPSRC), charities (Cancer Research UK) and commercial sources via collaborations with Pharmaceutical Companies. Externally, she plays a significant role in the NCRI Clinical and Translational Radiotherapy Research Working Group, where she currently chairs the Radcom initiative that aims to expedite novel drug radiation combinations into clinical trial.

Michael Yellin, MD, Celldex Therapeutics

Michael Yellin, MD, is VP, Clinical Science at Celldex, where he oversees the company's clinical immuno-oncology program, including FLT3L, agonist monoclonal antibodies to CD27 and CD40, and a NY-ESO-1 vaccine. Prior to joining Celldex in 2010, Dr. Yellin spent 9 years at Medarex where he was the medical director for the ipilimumab (MDX-010) melanoma program, including the Phase 3 study that led to ipilimumab's initial approval, as well as for several other Medarex programs in autoimmune diseases. Dr. Yellin received his MD degree from SUNY Downstate, did his internal medicine residency at California-Pacific Medical Center, and his rheumatology fellowship at Columbia University. During his academic career at Columbia, his interest was in cellular immunology and he and his colleagues in the Division of Rheumatology co-discovered CD40L (CD154), making the first anti-human CD40L monoclonal antibody.

Margaret K. Yu, MD, Janssen Research & Development, LLC

Margaret K. Yu, MD, is Vice President, Oncology Clinical Development, Global Head Prostate Cancer Portfolio. Dr. Yu joined Janssen prostate cancer clinical development team in 2010. She heads up the global drug development programs and aligns with the scientific, regulatory and commercial input to drive the growth of the Janssen prostate cancer franchise. Dr. Yu was previously faculty at the Huntsman Cancer Institute at the University of Utah and joined the pharmaceutical industry in 2007.

@FDAOncology

@AACR

@ASTRO_org

@CR_UK



Join the conversation with #RxRTCombos18