

Clinical Trial Endpoint Development for  
Locally Advanced Head and Neck Squamous Cell Carcinoma (HNSCC)  
Food and Drug Administration (FDA)  
Oncology Center of Excellence (OCE) Public Workshop (Virtual)  
Date: November 3, 2021  
Time: 12:00 PM to 5:00 PM (ET)



### Speaker/Panelist Biographies

#### Anup Amatya



Anup Amatya is a statistical reviewer in the Division of Biostatistics V. He is a member of various working groups and committees within the Office of Biostatistics and OCE. Prior to joining FDA, he served as an Associate Professor at the New Mexico State University. He received his Ph.D. in Biostatistics from the University of Illinois at Chicago.

#### Vishal Bhatnagar



Dr. Vishal Bhatnagar is a medical oncologist/hematologist and the Associate Director for Patient Outcomes in the OCE. His interests include patient reported outcomes, patient preference and incorporation of patient experience in oncology trials. His work focuses on the operational management of the OCE's Patient-Focused Drug Development, MD, is a medical oncologist/hematologist and the Associate Director for Patient Outcomes in the program. Additionally, Dr. Bhatnagar has a strong clinical interest in multiple myeloma and has previously served as an Office of Hematology and Oncology multiple myeloma scientific liaison. Dr. Bhatnagar received his BA in Political Science and his medical degree at the George Washington University. He completed his internal medicine residency and hematology/oncology fellowship at the University of Maryland.

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## Barbara Burtness



Dr. Barbara Burtness is the Professor of Medicine at the Yale University School of Medicine. She is co-leader of the Developmental Therapeutics Program, and director of the Head and Neck Clinical Research Program at Yale Cancer Center. Dr. Burtness received her MD from SUNY at Stony Brook. She completed an internship and residency at Yale-New Haven Hospital and fellowship training in oncology at Memorial Sloan Kettering Cancer Center.

Dr. Burtness' research focuses on translational studies in head and neck cancer, including biomarkers of resistance to EGFR inhibition, synthetic lethal approaches for HPV negative head and neck cancer, and immunotherapy. She chairs the ECOG-ACRIN Head and Neck Cancer Therapeutics Committee, which conducts multi-center trials of novel treatment paradigms to improve the survival and functional outcomes of patients with all stages of head and neck cancers. She has conducted numerous phase I–III investigator-initiated trials and was principal investigator of a pivotal trial leading to approval of immune checkpoint inhibition in first-line treatment of head and neck cancer.

Dr. Burtness is the Principal Investigator of the Yale Head and Neck Specialized Program of Research Excellence and has over 200 peer-reviewed publications in journals such as *Lancet*, *Journal of Clinical Oncology*, *Lancet Oncology*, *JAMA Oncology*, and *Clinical Cancer Research*.

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## Joseph Califano



Joseph A. Califano, III, MD, is a board-certified otolaryngologist who specializes in head and neck surgical oncology, and the integration of basic, molecular biologic research in that practice. His expertise includes minimally invasive treatment of tumors of the oral cavity, larynx, pharynx, thyroid, and neck to minimize cosmetic impact and maximize function, with an interest in tumors of the skull base, mouth, salivary glands, and premalignant conditions of the upper aerodigestive tract. Dr. Califano emphasizes a multidisciplinary approach and coordinating different areas of medical expertise to optimize the care for complex patients.

As the Physician-in-Chief for Moores Cancer Center at UC San Diego Health, Dr. Califano oversees clinical operations and all related inpatient and outpatient oncology services at UC San Diego Health, as well as operations with affiliates and outreach clinics. He participates in Board of Visitors and philanthropy meetings, and is appointed to the Cancer Center Executive Committee, where he works in partnership with the chief administration officer on operational and strategic opportunities that further the mission and vision of the cancer center.

Dr. Califano is a professor in the Division of Otolaryngology in the Department of Surgery at UC San Diego School of Medicine. As a world-class physician-scientist, he has translated multiple discoveries from laboratory to clinic, including the application of sequencing technologies to create an early detection method for HPV-related and other head and neck cancers.

He actively participates in several areas of investigation including integrative network based molecular analysis of head and neck tumors; detection of recurrent and occult cancer within blood and saliva using molecular biologic techniques; and defining the underlying biology of head and neck cancers. Dr. Califano also currently serves as the lead investigator for clinical trials that explore early detection of head and neck cancers and well as molecular detection of recurrence.

Dr. Califano directs a laboratory focused on the molecular biologic basis of head and neck cancer. He has published over 290 peer reviewed articles related to both the clinical and basic scientific aspects of cancer and serves on a variety of professional

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organizations and editorial boards, including the NCI Head and Neck Steering Committee, as well as the Council of the American Head and Neck Society. Prior to joining UC San Diego Health in 2015, Dr. Califano was a professor in the Department of Otolaryngology - Head and Neck Surgery at Johns Hopkins School of Medicine in Baltimore. Dr. Califano completed a fellowship in head and neck surgical oncology at Memorial Sloan Kettering Cancer Center and a residency in otolaryngology – head and neck surgery at Johns Hopkins Hospital. He earned his medical degree from Harvard Medical School and is board certified in otolaryngology.

## Mary Ann Caputo



Mary Ann Caputo is Executive Director of SPOHNC (Support for People with Oral and Head and Neck Cancer). She has been with SPOHNC for more than 15 years. With more than 20 years in the healthcare industry and prior experience at a Fortune 500 public company, Mary Ann has demonstrated her desire to help support this patient community through her experience as a Social Worker at Bellevue Hospital, NYC and a Finance Group Director at Revlon, Inc. She is passionate about her work supporting cancer patients, survivors, and their loved ones. Mary Ann is grateful to absorb inspiration from each person that has reached out to SPOHNC. She received her B.A. in Psychology from the City College of New York. Mary Ann is also on the editorial board of ASCO, and on the EAB SPORE for Head and Neck Cancer at the University of Pittsburgh Medical Center. Co-authored “The role of head and neck cancer advocacy organizations during the COVID-19 pandemic.” Yan, et. al. (2020). In 2020 Mary Ann was honored as one of Long Island’s “Top 50 Women in Business.”

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## Stephen Cassidy



Stephen Cassidy is a Stage IV Squamous Cell Head and Neck cancer survivor. He was diagnosed in the spring of 2016. Specifically, his cancer was T2N2a, P16+, P53+, P63+, and Cyclin D1 negative. A 2.2x2.2x2.2 cm tumor, scoring 14.8 SUV's, was on the base of his tongue. It had also spread locally to two lymph nodes on one side of his neck forming a 3.5x1.8 cm mass that scored 12.1 SUV's.

He completed 7-weeks of daily radiation at the local VA, plus Cisplatin chemotherapy, and three months later received a clean PET-scan.

Seven months later he began having back pain that ultimately turned out to be a metastatic spread of his original cancer to his ribs and liver. The rib tumor was "strongly and diffusely" P16 positive for metastatic disease, about 7x6x5 cm, scoring a 16.7 SUV's. The liver tumor was about 1 cm in diameter and 5.7 SUV's.

He then successfully completed 21 weeks of treatment, again at the VA, first with chemotherapy of Carboplatin and Fluorouracil plus Cetuximab then with radiation (20 sessions) and a liver embolization.

After completing this treatment, he was considered "stable" and elected to go into an Immunotherapy Trial at Moffitt Cancer Center receiving bi-weekly Cetuximab and Nivolumab, completing this treatment in May of 2020. He happily continues to be "stable." Mr. Cassidy resides in St. Petersburg, FL with his wife (a breast cancer survivor), dog (a toe cancer survivor), and two sons.

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## Ezra Cohen



Ezra Cohen, MD, is Chief of the Division of Hematology-Oncology, and Co-Director of the San Diego Center for Precision Immunotherapy. 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 co-developed a personalized neoantigen vaccine using unique cancer mutations to boost an anti-tumor 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

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Center. A dedicated educator, Dr. Cohen also mentored and developed young faculty in his program.

## Robert Ferris



Robert L. Ferris, MD, PhD is Hillman Professor of Oncology and Director at UPMC Hillman Cancer Center, Associate Vice Chancellor for Cancer Research, and Professor of Otolaryngology, of Immunology, and of Radiation Oncology. Dr. Ferris currently serves on the Editorial Boards of JNCI, JCO, Clinical Cancer Research, Cancer Immunology Research and Section Editor for Cancer. He is Editor in Chief of Oral Oncology. Dr. Ferris has published over 380 peer-reviewed manuscripts and book chapters.

Dr. Ferris's publications have been cited over 34,000 times producing an h-index of 91. He was re-elected co-chair of the NCI Head and Neck Steering Committee until 2021 to facilitate prospective clinical trials. Dr. Ferris has been the lead investigator of several practice-changing, prospective randomized trials, including Checkmate-141 which led to the FDA approval of Nivolumab immunotherapy for head and neck cancer, as well as ECOG 3311, testing radiation dose-deintensification after transoral robotic surgery (TORS) for HPV+ oropharynx cancer. The Ferris lab has been continuously funded by the NCI since 2005, focused on neoadjuvant "window" trials of immuno-oncology agents and biomarkers of response in the tumor microenvironment, collaborating with many early phase companies and therapeutic agents.

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## Amanda Hollinger



Amanda has served as Executive Director of the Head and Neck Cancer Alliance since 2018. With more than 20 years of experience in the nonprofit and public sector, Amanda has held leadership positions in a variety of organizations, including the YWCA of Greater Charleston, Trident Technical College, and as a nonprofit consultant. Her skills include fundraising, federal and foundation grant writing, advocacy, community outreach, and organizational development. Co-authored publications related to head and neck cancer include Yan, et. al. (2020).

The role of head and neck cancer advocacy organizations during the COVID-19 pandemic. *Head & Neck: Journal of the Sciences and Specialties of the Head & Neck* (Vol 42, Issue 7) and Reed, et. al. (2010. Oral Cancer Preventive Practices of South Carolina Dentists and Physicians. [Journal of Cancer Education](#) (Volume 25), pages 166–173.

Amanda received her bachelor's degree from Guilford College in Greensboro, North Carolina, and her Master's degree in Public Policy from the Humphrey School of Public Affairs at the University of Minnesota. In her free time, Amanda enjoys cooking, running, volunteering, reading, traveling, and spending time with family. Head and neck cancer has impacted the lives of family members close to her, and Amanda is committed to helping HNCA fulfill its vision of saving lives through prevention, education, and advocacy.

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## Kate Hutcheson



Dr. Kate Hutcheson is a Professor and Deputy Director of Clinical Research in the Department of Head and Neck Surgery with dual appointment in the Division of Radiation Oncology at the University of Texas MD Anderson Cancer Center. She serves as Section Chief and Research Director for the Section of Speech Pathology and Audiology. Dr. Hutcheson is a certified speech-language pathologist, a Board-Certified Specialist in Swallowing and Swallowing Disorders (BCS-S) and holds a Doctorate Degree in Epidemiology. She maintains an active clinical practice and research program. She has authored over 120 journal articles with funding support from the National Institutes of Health, Patient Centered Outcomes Research Institute, the MD Anderson Institutional Research Grant Award program, and the CPRIT UT Health Innovation Training Program. She is an accomplished clinician and educator who lectures nationally and internationally on radiation associated dysphagia and head and neck cancer rehabilitation.

## Zain Husain



Zain Husain, MD is an Associate Professor and Radiation Oncologist at Sunnybrook Health Sciences Centre/University of Toronto, where he specializes in the treatment of Head and Neck cancers and leads the Head and Neck Radiation Oncology Program. He also serves on the NCI Head and Neck Steering Committee Previously Untreated and Locally Advanced (PULA) Task Force, as well as the ECOG Head and Neck Core Committee. His research interests are in clinical trial design as well as in health outcomes research, particularly in relation to HPV-related oropharyngeal cancer. He started his career at the Yale School of Medicine where he was also director the Head and Neck radiotherapy program. Dr. Husain completed his residency at the University of

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Maryland, where he served as chief resident in his last year and graduated from medical school at the University of California, Irvine.

## Erin Larkins



After obtaining her degree in Molecular Biochemistry and Biophysics at Yale University, Dr. Larkins attended medical school at the Uniformed Services University of the Health Sciences as a Naval officer, graduating as an M.D. in 2000. She completed internship and residency training in Internal Medicine at the Bethesda Naval Hospital followed by fellowship training in Medical Oncology and Hematology at the National Cancer Institute in Bethesda, MD. She served as a medical oncologist and hematologist in the U.S. Navy for 8 years, caring for service members and their families and participating in the training of Internal Medicine residents and Hematology-Oncology fellows. In 2014, Dr. Larkins transferred to the US Public Health Service and came to work at the Federal Drug Administration (FDA) as a clinical reviewer for the Thoracic and Head & Neck Tumors Team in the Office of Oncologic Diseases. She became a Team Lead for the Thoracic and Head & Neck Tumors Team in 2017. She continues to provide clinical care to patients with lung and head & neck cancer as a volunteer at Walter Reed National Military Medical Center. She has also had personal experience with cancer in close family members.

## Quynh Le



Dr. Le 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

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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, and a member of ASTRO Nominating Committee. She also serves on many other national committees and as a reviewer for several cancer related journals.

## Ranee Mehra



Ranee Mehra, M.D. is the Director of Head and Neck Medical Oncology and Professor of Medicine at the Marlene and Stewart Greenebaum Comprehensive Cancer Center. Dr. Mehra received her undergraduate degree in Biology from the Massachusetts Institute of Technology in 1995 and went on to receive her medical degree from the New York University School of Medicine in 1999. Upon completing her internship and residency in Internal Medicine at the New York University Langone Medical Center, she later completed her clinical fellowship in Medical Oncology at Yale University in 2006. She went on to join the faculty at Fox Chase Cancer Center in Philadelphia, PA in 2006, where she was a clinical

investigator for head and neck and thoracic studies.

Prior to joining the Greenebaum Cancer Center, Dr. Mehra was Director of Head and Neck Therapeutics and co-Director of the Upper Aerodigestive Program at Johns Hopkins University. Dr. Mehra is a clinical investigator for the treatment of head and neck and thoracic cancers with immunotherapy and targeted therapies. Her research interests also include incorporation of biomarkers in clinical trial design and development therapeutics.

Dr. Mehra is a member of the American Society of Clinical Oncology and the Eastern Cooperative Oncology Group (ECOG) Head and Neck Committee. She is also a member of the NCI Head and Neck Recurrent/Metastatic Task Force.

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## Gautam Mehta



Gautam Mehta received his M.D. from Georgetown University in 2010. He completed Neurosurgery residency at the NIH and University of Virginia, followed by a Neurosurgical Oncology and Skull Base Surgery fellowship at M.D. Anderson Cancer Center. He was a member of the Neurosurgery faculty and Chair of the Research Committee at the House Ear Institute prior to joining FDA with the Division of Oncology 2 in 2020. He has published over 80 scientific papers and book chapters related to neuro-oncology and currently serves as the Scientific Liaison for Adult Neuro-Oncology at FDA, as an Associate Editor for the Journal of Neuro-Oncology, and as Chair of the Endolymphatic Sac

Tumors/Audiologic Screening Guidelines Subcommittee for the VHL Alliance. He is a member of the Executive Committee for the American Association of Neurological Surgeons/Congress of Neurosurgeons Section on Tumors

## Loren Mell



Dr. Mell is Professor and Vice Chair of Clinical & Translational Research for the University of California, San Diego Department of Radiation Medicine. He is Co-Director of the Hanna & Mark Gleiberman Head and Neck Cancer Center and Co-Chair of the NCI Head and Neck Steering Committee. He is principal investigator for numerous clinical trials and grants funded by the National Institutes of Health, private foundations, and industry, and is lead editor of the textbook, *Principles of Clinical Cancer Research*. An author of more than 250 scholarly publications, Dr. Mell's research

focuses on effects of radiation on the immune system, clinical trials of immunotherapy and image-guided radiation therapy, and personalized approaches to cancer treatment.

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## Pallavi Mishra-Kalyani



Pallavi Mishra-Kalyani, Ph.D. is a Team Leader in the Division of Biometrics V, Office of Biostatistics which supports Office of Oncology Drugs at the Center for Drug Evaluation and Research (CDER). Since joining the Food and Drug Administration (FDA) in 2015, Dr. Mishra-Kalyani has contributed to the efforts to understand and address the statistical issues related to the potential use of Real-World Data and Real-World Evidence for regulatory purposes. Her research interests include statistical methods for observational data, causal inference, and non-randomized trial design. She has participated at several statistics and oncology workshops, conferences, and working groups on these topics. Dr. Mishra-Kalyani received her Ph.D. in Biostatistics from Emory University and her Master's degree in Epidemiology from the T.H. Chan School of Public Health at Harvard University.

## Cheri-Ann Nathan



Cherie-Ann Nathan, MD, FACS, is the Jack W. Pou Endowed Professor and Chairman of the Department of Otolaryngology/Head and Neck Surgery at LSU-Health in Shreveport. She is also Director of Head and Neck Oncologic Surgery and Research at the Feist-Weiller Cancer Center and has a gratis appt. in the Dept. of Biochemistry & Molecular Biology. She completed her Otolaryngology/Head and Neck Surgery residency and head and neck fellowship in 1995 at University of California, San Diego. She was a post-doctoral fellow at Johns Hopkins where she started her research career. Following her fellowship, she began her academic career at LSU-Health Sciences Center, Shreveport. Her passion to improve outcomes for patients with head and neck cancer was the reason she moved from Mumbai India, where she went to medical school. She is a Surgeon-Scientist that maintains a busy practice treating head and neck cancer, thyroid, parathyroid, salivary gland tumors and skin cancer and she also leads an active research team.

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The National Cancer Institute has funded her translational research since 2000 and her work focuses on targeted therapy for head and neck squamous cell cancer patients.

She is recognized nationally and internationally for her seminal work on molecular analysis of surgical margins. She has pioneered multi-institutional clinical trials using mTOR inhibitors in HNSCC patients. She has also received NIH funding for chemoprevention of cancer with curcumin and has a patent for a curcumin chewing gum. Her current RO1 "Targeting the FGFR-2 pathway for cutaneous SCC" holds potential for patients with aggressive cSCC. She has published extensively, has over 220 publications in peer-reviewed journals, and has authored multiple textbooks and encyclopedia chapters. She has given over 200 invited national and international lectures.

## David Pfister



David G. Pfister, MD received his MD from the University of Pennsylvania, where he completed a residency in internal medicine at the Hospital of the University of Pennsylvania. He was a Robert Wood Johnson Clinical Scholar and trained in clinical epidemiology at Yale University, and did a fellowship in medical oncology and hematology at Memorial Sloan Kettering Cancer Center (MSKCC). Dr. Pfister holds the ranks of Professor of Medicine at Weill Cornell Medical College and Member at MSKCC, where he is Chief of the Head and Neck Oncology Service within the Department of Medicine and Co-leader of the Head and Neck Cancer Disease Management Team.

He is also Associate Deputy Physician-in-Chief for Strategic Partnerships at MSKCC. Dr. Pfister is an internationally recognized expert in the management of head and neck tumors, and has pioneered the development of combined modality, "organ preservation", treatment programs, intended to preserve function and cosmesis without compromise in survival. He is the 2011 recipient of the Willet F. Whitmore Award for Clinical Excellence at MSKCC. Dr. Pfister has previously served in an editorial capacity for both *Clinical Cancer Research* and the *Journal of Clinical Oncology*.

In addition to the development of combined modality-organ preservation therapies, his current research focuses on the evaluation of targeted and immunotherapies, the development of innovative therapies for rare tumors, and healthcare outcome assessments. Dr. Pfister is a member of the Board of Directors for the National Comprehensive Cancer Network (NCCN) and is Chair of the NCCN's Head and Neck

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Cancer Practice Guidelines Panel. He is former Chair of the Protocol Committee for the International Thyroid Oncology Group (ITOG), and former member of the Executive Committee of the Board for that organization.

He is past Co-chair of the Head and Neck Cancer Recurrent/Metastatic Disease Task Force at the National Cancer Institute (NCI). He is a member of the Medical Advisory Board for Support for People with Oral and Head and Neck Cancer (SPOHNC).

## Nabil Saba



Dr Saba is the Lynn and Howard Halpern Chair in Head and Neck Cancer Research, Professor and Vice Chair of Hematology Medical Oncology, adjunct Professor of Otolaryngology, and co-Director of the Head and Neck Cancer Multi-Disciplinary program at the Winship Cancer Institute Emory University. He has worked on exploring novel therapeutic approaches in head and neck cancers and published extensively in this field. He is a recognized international leader in the field of head and neck cancer clinical research especially in the area of EGFR targeting and immunotherapeutic applications. Dr Saba served as

the principal investigator of more than 50 interventional and translational clinical trials and currently chairs two cooperative group clinical trials in the field of head and neck oncology under the ECOG-ACRIN group. He is an elected member of the ASCO clinical guidelines committee and the HN guidelines committee. He received competitive NIH funding investigating novel genomic approaches in HPV related and unrelated OPCA and is the recipient of intramural funding studying this disease. He has been elected chair of the recurrent metastatic as well as rare tumor Task Forces of the Head and Neck Cancer NCI steering committee. Dr Saba has published more than 150 peer reviewed manuscripts and textbook chapters and is the editor of a textbook updating the management of esophageal cancer.

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## Jeffery Shoop



Jeffery Shoop is a survivor of Stage 4 HPV Head and Neck cancer in 2012 and a Clinical Trial Immunotherapy (Pembrolizumab) patient survivor in 2016. He is also a Patient Advocate with NRG Oncology Head & Neck Cancer Committee and the NCI Head & Neck Steering Committee. Jeffery is a member of Support for People with Oral Head and Neck Cancer (SPOHNC) chapter in Hershey PA, and a member of Reel Recovery Org.

## Sharon Spencer



Sharon A. Spencer, MD is Professor of Radiation Oncology at the University of Alabama at Birmingham (UAB), where she also holds the position of Ruby Meredith Outstanding Clinician in Radiation Oncology Endowed Chair. Dr. Spencer also serves as Clinical Director of UAB's Department of Radiation Oncology and Chief of Medical Services for the radiation therapy program at the UAB School of Health Professions.

Dr. Spencer earned her medical degree and masters of science degree in health administration from the University of Alabama at Birmingham, where she also completed her internship and residency. She is board-certified in radiation oncology.

Dr. Spencer's interests include the translation of novel radio therapeutic treatments into clinical practice for brain, head and neck, and lung tumors. Her clinical work aims to maximize the additive benefit of combination therapy and reduce associated toxicity by combining drugs with refined radiotherapy planning and delivery. In her current role, Dr. Spencer helps coordinate research and patient programs between her department and

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others, including medical oncology and surgery. She also serves as an advisor to minority students at UAB and the UAB School of Medicine

Dr. Spencer serves on several councils and committees, including the Eastern Cooperative Oncology Group-ACRIN and NRG Head and Neck Committees. Additionally, Dr. Spencer is an active member of the Radiological Society of North America, the American Association for Cancer Research, the American Society of Therapeutic Radiology and Oncology, and the American Society of Clinical Oncology. She previously served on the National Cancer Institute Metastatic Head and Neck Task Force and is a past recipient of the American Cancer Society Life Inspiration Award.

Dr. Spencer is Vice Chair of the NCCN Head and Neck Cancers Panel and serves as the panel's imaging and radiation reviewer. She also is a member of the NCCN Smoking Cessation Panel.

## Liza Stapleford



Dr. Stapleford is a board-certified radiation oncologist who currently works at the FDA in the Center for Devices and Radiological Health. She received her medical degree from Tufts University and went on to complete her internship in internal medicine and residency training in radiation oncology at Emory University. Dr. Stapleford worked as a radiation oncologist in both urban and rural settings for ten years. She was founding partner of Northwest Georgia Radiation Oncology after working as an Assistant Professor at Emory University specializing in thoracic and aerodigestive malignancies. While on faculty at Emory, she helped develop a multi-disciplinary lung cancer clinic, participated in cancer quality control and radiation safety committees, and conducted research in the technical aspects of radiation delivery, treatment response assessment, and image-guided treatments.

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## Paz Vellanki



Dr. Vellanki obtained her MD/PhD at the University of Maryland. Her doctoral research in biochemistry focused on the structure and function of the DNA repair enzyme, Mut Y Homolog, in which germline mutations are associated with a hereditary colorectal cancer syndrome. She completed her Internal Medicine Residency at Wake Forest University and subsequently was at Johns Hopkins University for fellowship training in Medical Oncology, during which time she studied genetic risk factors for head and neck squamous cell carcinoma. Her current interests include clinical trial design and emerging biomarkers such as circulating tumor DNA. She is currently an Acting Team Lead for the Thoracic and Head and Neck Cancer Team at the FDA. She continues to provide clinical care to patients with head and neck cancer and lung cancer at the University of Maryland.

## Jared Weiss

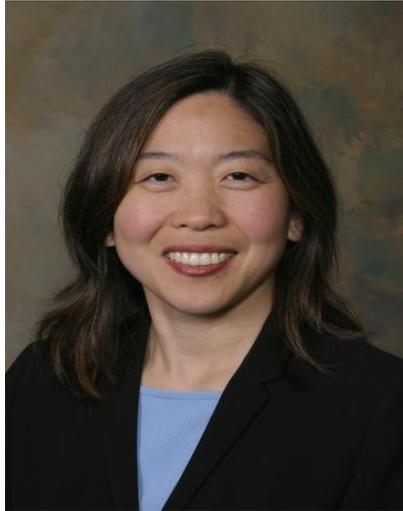


Dr. Weiss received his undergraduate degree from Brown University and medical degree from Yale University. He completed residency at Harvard's Beth Israel Deaconess Medical Center then fellowship at the Hospital of the University of Pennsylvania. He is currently employed as an associate professor of medicine at UNC's Lineberger Comprehensive Cancer Center where he also serves as finance director for the clinical protocol office and section chief of thoracic and head/neck oncology. Dr. Weiss is proud to volunteer for and serve as vice president for cancergrace.org and to advocate with the Lung Cancer Initiative of North Carolina. Dr. Weiss's research is focused on personalized and adaptive immunotherapy to treat cancer.

Clinical Trial Endpoint Development for  
Locally Advanced Head and Neck Squamous Cell Carcinoma (HNSCC)  
Food and Drug Administration (FDA)  
Oncology Center of Excellence (OCE) Public Workshop (Virtual)  
Date: November 3, 2021  
Time: 12:00 PM to 5:00 PM (ET)



## Sue Yom



Dr. Sue S. Yom, MD, PhD, MAS, FASTRO is the Vice Chair of Strategic Advisory and the Irwin Mark Jacobs and Joan Klein Jacobs Distinguished Professor in the Departments of Radiation Oncology and Otolaryngology - Head and Neck Surgery at the University of California San Francisco. She earned an MD and English PhD from the University of Pennsylvania and completed residency in radiation oncology at the University of Texas M. D. Anderson Cancer. She currently serves as Editor-in-Chief of the International Journal of Radiation Oncology Biology Physics, Chair of the NRG Oncology Head and Neck Cancer Committee, and Guidelines and Protocols Committee Co-Chair for the Head and Neck Cancer International Group.

She is Immediate Past President of the American Radium Society. She is a member of the NCCN Head and Neck Cancers guidelines committee and the Head and Neck Cancer Resource Panel, Education, and Science Education Committees of the American Society of Radiation Oncology.

She was previously the founding Chair of the Appropriate Use Criteria Committees of the American Radium Society, national Chair of the American College of Radiology Appropriateness Criteria Radiation Oncology committees, written and oral board examiner for the American Board of Radiology, member of the NCI Head and Neck Recurrent/Metastatic Disease Task Force, and Co-Chair of the National Cancer Institute's Head and Neck Steering Committee.

Dr. Yom's research interests include clinical trials of late-stage radiosensitizers, immunotherapies, novel imaging, and radioprotectants, and patient-oriented supportive care, quality of life, and decision support studies. She has been author or co-author on over 250 manuscripts and book chapters. She is a frequent plenary speaker and media commentator and serves on organizing committees for numerous radiation oncology and head and neck and lung cancer professional societies.