

**Non-Muscle Invasive Bladder Cancer Workshop**  
**Day 2: November 19, 2021 9:00 AM - 12:00 PM ET**  
Virtual

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## Biographies

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### Workshop Day 2 Opening Remarks

#### Chana Weinstock, MD



Chana Weinstock, MD is a medical oncologist and hematologist specializing in genitourinary (GU) oncology. She has been a GU oncology team leader at the U.S. Food and Drug Administration since 2017. She is a graduate of University of Toronto (with high distinction) and the Albert Einstein College of Medicine. She has practiced thoracic and genitourinary oncology at the University of Maryland Medical Center and at the Baltimore Veterans' Affairs Medical Center, where she remains on staff. Her original oncology research has been published in journals such as the JCO, Journal of Urology, and Clinical Cancer Research, and she has presented at national meetings including ASCO, ASTRO, RSNA, SABCS, and CAMO, including oral presentations at ASCO, ASCO GU symposium, and at ASTRO workshops. She served as the track leader of ASCO's GU oncology kidney and bladder cancer educational track in 2021 and remains on the educational committee and serves on the Bladder Cancer Advocacy Network (BCAN) Annual Meeting planning committee. She has recently been involved in organizing several workshops and minisymposia on clinical trial design and endpoint definition in GU oncology.

### Session 4: Carcinoma in Situ (CIS)

#### Sundeep Agrawal, MD (Presenter)



Sundeep Agrawal, MD, is a board-certified medical oncologist and currently serves as team lead for genitourinary malignancies in the Food and Drug Administration (FDA) Center for Drug Evaluation and Research, Division of Oncology. He is also the clinical lead for Project Renewal within the Oncology Center of Excellence (OCE), evaluating evidence and providing clinical input for this public health initiative that aims to update the safety and efficacy labeling information for older oncology products. He completed his internal medicine residency training at Drexel University College of Medicine and completed fellowship in hematology and oncology at Washington Hospital Center/Georgetown University Hospital. His research interests include novel clinical trial designs and methods to expedite drug development, the treatment of genitourinary malignancies, and the application of technology to promote advances in oncology clinical trials. He still sees patients on a part-time basis.

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# Biographies

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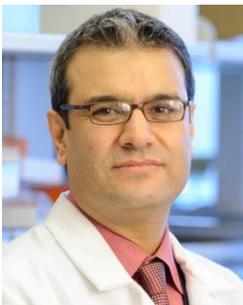
## Peter Black, MD (Presenter)



Peter Black is a Urologic Oncologist at Vancouver General Hospital, a Research Scientist at the Vancouver Prostate Centre, and Professor in the Department of Urologic Sciences at the University of British Columbia. Peter has a clinical subspecialty interest in bladder and prostate cancer and a research program dedicated to urothelial carcinoma. He is editor-in-chief of the *SIU Journal*.

Twitter: @pcvblack

## Hikmat Al-Ahmadie, MD (Presenter)



Dr. Al-Ahmadie is a genitourinary pathologist at Memorial Sloan Kettering Cancer Center. His clinical focus is on the diagnosis of tumors of the GU system and his academic and research focus is the pathology and molecular biology of urothelial neoplasia. He is a graduate of Damascus University Faculty of Medicine. He trained in Anatomic and Clinical pathology at the American University of Beirut and the University of Cincinnati College of Medicine, followed by fellowship training in Oncologic Pathology and Genitourinary Pathology. His main research focus is on the investigation of the molecular basis for the development and progression of urothelial carcinoma and the

mechanisms responsible for the pathologic and clinical heterogeneity commonly identified in bladder cancer. He is an NIH-funded investigator and serves as the Director of the Biospecimen Core for the MSKCC SPORE in Bladder Cancer. He was also one of the lead pathologist for the Bladder Cancer Analysis Working Group of The Cancer Genome Atlas (TCGA).

## Jaleh Fallah, MD (Moderator)



Dr. Fallah is a medical oncologist at the Division of Oncology 1, Genitourinary Cancers, US FOOD & Drug Administration (FDA). Dr. Fallah received her M.D. from Isfahan University of Isfahan in Iran. She then moved to the United States, where she completed her Internal Medicine residency at Brown University and her Hematology and Oncology fellowship at Cleveland Clinic. Her clinical interests are GU malignancies, brain metastasis, and biomarkers. During her fellowship training, she wrote protocols for several clinical trials in bladder cancer and brain tumors. Upon completion of her fellowship training in 2020, she joined FDA as a clinical reviewer. During this time, she has evaluated trial designs as well as safety and efficacy of therapeutics in all stages of clinical development from pre-investigational new drugs through

marketing approvals and has worked on several exploratory pooled analyses.

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## Biographies

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### Session 4 Panelists

#### Kamal Pohar, MD



Dr. Kamal Pohar is Associate Professor and Vice Chair for Faculty Affairs in the Department of Urology at The Ohio State University. He also holds the Julius and Diana Skestos Endowed Chair in the Department of Urology. Dr. Pohar's clinical practice is exclusively focused on the treatment of patients with urothelial cancer. His translational research interest is focused on studying a family of transcription factors that modulate the tumor microenvironment (TME) during the various stages of bladder cancer and investigator initiated clinical trials focused on TME. Dr. Pohar is also the site-PI on numerous national clinical trials in the bladder cancer space, both cooperative group and industry supported and consistently demonstrates high patient accruals to open trials. He is an active member providing service to a number of organizations supporting efforts in bladder cancer including the American Urological Association (AUA), National Comprehensive Cancer Network (NCCN), Society for Immunotherapy for Cancer (SITC) and the International Bladder Cancer Group (IBCG).

#### Sundeep Agarwal, MD

(See above)

#### Peter Black, MD

(See above)

#### Hikmat Al-Ahmadie, MD

(See above)

### Session 5: Papillary

#### Colin Dinney, MD (Presenter)



Dr. Dinney is Professor and Chairman of Urology served as the Director of MD Anderson's Bladder Cancer SPORE from 2001 -2019. He maintains an active clinical practice specializing on bladder cancer and a research laboratory focused on understanding the biology of bladder cancer metastases and on the development of novel therapy for bladder cancer. His group played a pioneering role in developing preclinical models of spontaneous bladder cancer metastasis and used these models to identify the mechanisms regulating metastasis and for preclinical therapeutic studies.

His group developed intravesical Nadofarigene Firadenovec (adenoviral mediated interferon- $\alpha$  gene therapy) for the treatment of BCG Unresponsive NMIBC. A Phase 3 trial was conducted by the SUO-CTC. Currently his laboratory is working to improve interferon gene therapy by identifying biomarkers

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## Biographies

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that predict sensitivity or resistance, by testing novel vectors that might improve transfection efficiency and activity, and by evaluating novel combination strategies.

Dr. Dinney served on the Society of Urologic Oncology Executive Committee and was the Founding President of the SUO's Clinical Trial Consortium and is the current Chair of the SUO CTC Bladder Cancer Committee. Dr Dinney is the SPORE's Liaison to SWOG's GU Executive Committee. He is also a former member of the National Institutes of Health, Genitourinary Steering Committee, and served as the Urology Chair for the Bladder Cancer Task Force from 2016-2019.

### Zhou Feng, PhD (Presenter)



Zhou Feng, PhD is a mathematical statistician in the Office of Biostatistics at the Center of Drug Evaluation and Research of the US Food and Drug Administration, whose expertise includes statistical design and analysis of clinical trials, dose regimen assessment in early phase oncology trials, causal inference using propensity score methods with real world data, and Bayesian inference. Dr. Feng received his PhD from UMBC in 2020 where he developed methods for causal inference allowing covariate measurement error and/or non-directly observable outcome.

Dr. Feng's work focuses on the review of new drug applications and investigational new drug applications in oncology. Meanwhile, he reviews research proposals submitted to the FDA Broad Agency Announcement, serves as an advisor on RWE collaborations, and participates in multiple internal research projects.

### Noah Hahn, MD (Moderator)



Dr. Hahn is a professor of Oncology and Urology at the Johns Hopkins University School of Medicine. He serves as the Director of the Medical Oncology Bladder Cancer Program and the Deputy Director of the Johns Hopkins Greenberg Bladder Cancer Institute. Dr. Hahn is an internationally recognized authority in the conduct of bladder cancer novel therapeutic clinical trials and translational investigations.

He maintains an active clinical practice and sees patients with urothelial cancers of all locations and stages including non-muscle invasive bladder cancer. Dr. Hahn's clinical and translational research interests focus on improving outcomes for patients with urothelial cancers through: 1) The development of novel epigenetic, targeted, and immunomodulatory approaches to treat and prevent urothelial cancer; 2) The credentialing of the naturally-occurring, immunocompetent canine-human tumor model as a relevant comparative oncology model optimal for the pre-clinical study of candidate human urothelial cancer biomarkers and therapeutics; and 3) The identification and validation of predictive biomarkers relevant to urothelial cancers.

In addition to his efforts at Johns Hopkins, Dr. Hahn serves as the bladder cancer chairman of the Eastern Cooperative Oncology Group - American College of Radiology Imaging Network (ECOG-ACRIN), participates on the NCI Bladder Cancer Task Force, and serves on the scientific advisory board of the Bladder Cancer Advocacy Network.

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# Biographies

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## Session 5 Panelists

### Tracy Downs, MD, FACS



Tracy M. Downs, MD, FACS, is a Professor of Urology and our inaugural Chief Diversity & Community Engagement Officer at UVA Health. Tracy is a leader of integrity who is passionate about the work of diversity, equity, and inclusion as well as community health advocacy.

He also is a board-certified urologist specializing in the surgical treatment of urologic cancers, with a sub-specialty focus in the treatment of both prostate and bladder cancer. He also served as Faculty Director of the Cancer Health Disparities Initiative at the University of Wisconsin's Carbone Comprehensive Cancer Center.

Tracy earned his MD from the University of California San Diego, completed his residency in urology at Brigham & Women's Hospital in Boston, and completed a fellowship in urologic oncology at the University of California at San Francisco.

### Seth Lerner, MD



Seth P. Lerner, MD, is Professor of Urology and holds the Beth and Dave Swalm Chair in Urologic Oncology, and is Vice-chair for Faculty Affairs in the Scott Department of Urology, Baylor College of Medicine. He is Director of Urologic Oncology and the Multidisciplinary Bladder Cancer Program. He earned his medical degree from Baylor College of Medicine, completed a surgical internship at Virginia Mason Hospital in Seattle, and returned to Baylor for his residency training. He completed a two-year fellowship at the University of Southern California in urologic oncology and reconstructive surgery under Peter Jones and Don Skinner before returning to join the full-time Baylor faculty in

1992. His clinical practice, education, and research activities are devoted to urologic oncology and particularly lower and upper tract urothelial cancer. Dr. Lerner is author of 220 peer-reviewed articles, and co-editor of a comprehensive *Textbook of Bladder Cancer*. He is the founding co-editor-in-chief of the Bladder Cancer journal. He established and directs the multi-disciplinary Bladder Cancer Research Program at Baylor and his research interests include use of selective estrogen receptor modulators for treatment of bladder cancer, gene therapy, integrated proteogenomic analysis of bladder and upper urinary tract cancers, and outcomes of radical cystectomy and pelvic lymphadenectomy. He has 29 years of experience as a clinical investigator for both NCI and industry funded clinical trials. He is the PI of the ongoing SWOG NCI Phase III trial comparing extended vs. standard pelvic lymphadenectomy at time of radical cystectomy. He is active in the leadership of several national bladder cancer research enterprises including chair of the Local Bladder Cancer committee of SWOG, founding and former co-chair of the NCI Bladder Cancer Task Force and current co-chair of the NCI CTEP Genitourinary Steering Committee, and he co-chaired the Analysis Working Group of The Cancer Genome Atlas Project for muscle invasive bladder cancer for. He was recently appointed to a 4 year term to the NCI Clinical Trials and Translational Research Advisory Committee. He is very active in the Bladder Cancer Advocacy Network (BCAN) as a member of the Board of Directors, past chair of the Bladder Cancer Think Tank and co-chair of the management committee of the Bladder Cancer Research Network. Dr. Lerner is an

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## Biographies

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active member of the prestigious American Association of Genitourinary Surgeons and is listed routinely among “America’s Top Doctors” and “Best Doctors in America.”

### **Sima Porten, MD**



Sima Porten received her undergraduate, doctoral and public health degrees from Northwestern University completing her education in June 2006. She was inducted into the Alpha Omega Alpha Honor Society during that time. She then completed her urology residency training at University of California, San Francisco where she received the Julius R. Krevans Award for Clinical Excellence. She then completed her Urologic Oncology Fellowship at The University of Texas, MD Anderson Cancer Center. During fellowship, she was awarded the John Quale Travel Fellowship for her research in Bladder Cancer. Currently, she is part of the multidisciplinary urologic oncology team of the UCSF Helen Diller

Family Comprehensive Cancer Center as an Associate Professor in Urology, where she continues to pursue her clinical interests in the diagnosis and treatment of bladder cancer, upper tract urothelial cancer, and high-risk prostate cancer. Dr. Porten’s research interests focus mainly on the diagnosis and management of urothelial carcinoma (bladder and upper tract). In studying the biologic basis of urothelial carcinoma using genomic techniques, Dr. Porten hopes to develop new tests and novel therapeutics to bring personalized medicine to patients with bladder cancer.

### **Colin Dinney, MD**

(See above)

### **Zhou Feng, PhD**

(See above)

## **Session 6: Patient-Focused Drug Development**

### **Angela Smith, MD (Presenter)**



Angela Smith received her medical degree and Masters of Science in Clinical Research from the University of North Carolina, where she also completed her urology residency. She is the Director of Urologic Oncology at the UNC Lineberger Comprehensive Cancer Center where she treats GU malignancies, including bladder, prostate and kidney cancer.

Dr. Smith has a background in health services research and biostatistics with particular interests in patient-centered outcomes research, risk stratification, and quality of care for invasive bladder cancer. She is the co-PI for a PCORI large pragmatic trial in BCG refractory bladder cancer, PI for a PCORI Engagement

Award with the Bladder Cancer Advocacy Network to engage patients in the research process, and has been funded by an AHRQ K08 grant that integrates patient-reported outcomes into post-cystectomy care through mobile health technology. She has previously served on the PCORI Advisory Panel for the Assessment of Prevention, Diagnosis and Treatment Options, representing clinicians. Dr. Smith also

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## Biographies

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serves as the Assistant Secretary of the American Urological Association and is on the AUA Quality Improvement and Patient Safety Committee, Scientific Advisory Board for the Bladder Cancer Advocacy Network, Journal of Urology Editorial Board, and chair of the Urology Care Foundation Bladder Health Committee.

### Neeraj Agarwal, MD (Moderator)



Dr. Neeraj Agarwal is a Professor of medicine, and a Presidential Endowed Chair of Cancer Research at the Huntsman Cancer Institute (HCI), University of Utah. He also directs the Genitourinary Oncology (GU) Program, and the Center of Investigational Therapeutics (CIT) at the HCI.

Dr. Agarwal is an internationally recognized physician scientist in the field of genitourinary cancers. He is the overall study chair of multiple Phase I/II and Phase III trials, and serves as a steering committee member of numerous other trials. He has received SWOG Young Investigator Award, the William D. Odell Young Investigator Award, and a National Cancer Institute Cancer Clinical Investigator Team Leadership Award. After receiving his medical training at the All India Institute of Medical Sciences in New Delhi, he completed a residency in internal medicine and a fellowship in geriatric medicine at the University of Iowa, followed by a hematology-oncology fellowship at HCI.

Dr. Agarwal has authored more than 300 peer-reviewed articles and book chapters. He serves as a panel member for the NCCN guideline committees for bladder and kidney cancers. He is an advisor to the Oncology Drug Advisory Committee and the United States Food and Drug Administration, and leads early therapeutics in the SWOG genitourinary cancers committee. He holds numerous scientific communications leadership roles, including chief editor of the *ASCO Daily News*, specialty editor for ASCO's [cancer.net](http://cancer.net) site, and editorial board member of several journals, including *Journal of Clinical Oncology*. He also serves as a member of the ASCO Genitourinary Cancers Advisory Panel. Recently, Dr. Agarwal was appointed as the Senior Director for Clinical Research Innovation, directly reporting to the cancer center director at the Huntsman Cancer Institute.

### Session 6 Panelists

#### Rick Bangs, MBA, PMP



Rick Bangs, MBA/PMP, is a bladder and prostate cancer survivor and has worked as a patient advocate in a variety of roles, including research advocacy, government lobbying, educational support, support groups, one-on-one support, and fundraising.

He serves as Chair of the SWOG Patient Advocate Committee and the SWOG Bladder Cancer Patient Advocate, the Bladder and Penile Cancer Patient Advocate for the National Comprehensive Cancer Network (NCCN), and as a Patient Advocate on ASCO and AUA Guideline Panels. He also supports the

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## Biographies

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Bladder Cancer Advocacy Network and Stand Up to Cancer. He is a retired Marketing and IT professional.

### **Vishal Bhatnagar, MD**



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.

### **Ken Brothers**



Ken Brothers was first diagnosed with Muscle Invasive Bladder Cancer (MIBC) in 2011 and entered his first clinical trial in 2012. Since that time, he has been screened/enrolled on a number of other trials, as well as undergone surgical intervention. A patient advocate and retired patent lawyer, Ken is the author of "Ken's Cancer Blog" and serves on the NCI Bladder Cancer Task Force.

### **Sarah Psutka, MD, MSc**



Dr. Sarah Psutka MD, MSc is an Associate Professor of Urology in the Department of Urology at the University of Washington. She holds a co-appointment at the Seattle Cancer Care Alliance and is a member of the Fred Hutchinson Cancer Consortium. She received her undergraduate and medical degrees from Harvard University and urology residency training at the Massachusetts General Hospital. She completed a Society of Urologic Oncology Fellowship in Urologic Oncology at the Mayo Clinic, and concurrently obtained her Masters' in Clinical and Translational Science. She previously served as the Director of Urologic Oncology at the John H. Stroger, Jr. Hospital of Cook County with a co-appointment as an Assistant Professor in Urology at the Northwestern Feinberg School of Medicine, prior to joining the faculty of the University of Washington.

Dr. Psutka's clinical efforts focus on minimally-invasive and complex open urologic oncology, with a particular interest in advanced kidney cancer, particularly venous tumor thrombus, testicular cancer,

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## Biographies

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and bladder cancer. She leads the urologic oncology program at Harborview Medical Center and is the Associate Program Director of the UW Society of Urologic Oncology Fellowship Program.

Dr. Psutka's research focuses on the study and development of personalized, comprehensive risk stratification measures in patients with advanced urologic malignancies. She leads research funded by the Bladder Cancer Advocacy Network to study the integration of comprehensive geriatric assessments, body composition, and psychometric capital assessments in patients with advanced bladder cancer with a focus on patient-reported outcome research and development of prehabilitation interventions. She leads multiple clinical trials and is a member of the Board of Directors of the Society of Urologic Oncology Clinical Trials Consortium and the SWOG Clinical Trials Survivorship Committee. She is the Senior Editor for the Urologic Oncology Section of the AUA Core Curriculum, is on the Editorial Board of Bladder Cancer and is an Associate Editor for European Urology. She was a founder of the Society of Women in Urologic Oncology of which she is the current President.

### **Angela Smith, MD**

(See above)

## **Wrap-up Day 2**

### **Elaine Chang, MD**



Elaine Chang, MD is a medical oncologist at the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Oncologic Diseases (FDA). She completed her hematology/oncology fellowship at Baylor College of Medicine and joined FDA in 2018.

She is serving as one of the Acting Team Leads for the Genitourinary Malignancies Team in Division of Oncology 1. Her research has focused on novel endpoints in renal, bladder, and prostate cancer. She has an interest in facilitating multi-stakeholder discussions on clinical trial design and rational drug development strategies that address unmet needs.