



2019 Program Schedule

August 8-10, 2019 | Washington, DC

Collaborating to Move Research Forward

Thursday, August 8

- 11:00 – 1:00 Patient Advocacy Session (for patient advocates only)
- 12:00 – 4:00 *Save-the-Date*: FDA/CDER and BCAN workshop on endpoints for the development of neoadjuvant systemic therapy regimens for muscle-invasive bladder cancer (separate registration required)
- 2:00 – 4:00 Think Tank Registration
- 4:00 – 5:00 Opening Remarks and Introductions
- 5:00 – 6:00 **Keynote Address** | Deborah K. Mayer, PhD, RN, AOCN, FAAN, Interim Director of NCI's Office of Cancer Survivorship
- 6:00 – 9:00 Founders Reception and Dinner

Friday, August 9

- 7:00 – 8:00 Breakfast
- 8:00 – 10:00 **Integrating Palliative Care into the Management of Bladder Cancer Patients**
Co-Chairs: Mary W. Dunn, RN, MSN, OCN, NP-C, University of North Carolina Chapel Hill, Renata Louwers, BCAN Advocate, and Robert Svatek, MD, UT Health San Antonio
- Palliative care, provided by a specially-trained team, is appropriate at any age and at any stage in a serious illness, and can be provided along with curative treatment. This engaging and interactive session includes presentations by both palliative care and bladder cancer experts focusing on providing relief from the symptoms and stress of the disease. Case studies will demonstrate how to bring palliative care "downstream" to bladder cancer patients at all stages of bladder cancer.
- 10:00 – 11:00 **2019 John Quale Travel Fellow (JQTF) Presentations**
- 11:00 – 11:15 Break

11:15 – 1:00

Lunch – 2017 Bladder Cancer Research Innovation Award Presentation

Seth P. Lerner, MD, FACS, Baylor College of Medicine. “Proteogenomic characterization of muscle-invasive bladder cancer to identify mechanisms of resistance and targets for therapy.”

1:00 – 3:00

FDA and the Bladder Cancer Community - Collaborating to Improve Outcomes

Co-Chairs: Chana Weinstock, MD, FDA, Seth Lerner, MD, Baylor College of Medicine, and Andrea Apolo, MD, NIH

The FDA Oncology Center of Excellence (OCE) leverages the combined skills of regulatory scientists and reviewers with expertise in drugs, biologics, and devices (including diagnostics). This panel will review the structure of the OCE and how expedited programs within the FDA strive to accelerate oncology drug development. Additionally, we will present summaries of previous collaborative workshops between the FDA and the multi-disciplinary bladder cancer community. This panel presents ongoing engagement between relevant bladder cancer stakeholders as the next generation of clinical trials are designed. The regulation of biomarkers, imaging, and devices in bladder cancer by the FDA will also be discussed.

3:00– 3:30 Break

3:30 – 5:00 **Breakout Sessions (page 4)**

5:30-7:30 Happy Hour & JQTF Poster Session - hosted by BCAN CEO

Saturday, August 10

7:00 – 8:00 Breakfast

8:00 – 10:00 Computational Biology: Emerging Applications for Translational Discoveries in Bladder Cancer

Co-Chairs: Gopa Iyer, MD, Memorial Sloan Kettering Cancer Center and Eliezer “Eli” Van Allen, MD, Dana Farber Cancer Center

Applying data-analytical and theoretical methods, mathematical modeling and computational simulation techniques, this panel will highlight how computational biology approaches have resulted in fundamental insights into the biology of bladder cancer. We will review how analysis of the urothelial Cancer Genome Atlas using these computational tools identified several genomic and epigenetic aberrations and mutational signatures thought to be important for bladder cancer development and prognosis. Speakers will also discuss the application of gene expression analysis to define molecular subtypes in bladder cancer with prognostic and predictive value as well as to delineate the tumor/immune microenvironment.

10:00 – 11:30 BCAN 2018 Young Investigator Award Research Presentations

Tracy Rose, MD, MPH, University of North Carolina, Chapel Hill
Philip Abbosh, MD, PhD, Fox Chase Cancer Center
David Oh, MD, PhD, University of California, San Francisco
Eugene Lee, MD, PhD, University of Kansas Health System

11:30 – 1:00 Lunch

Survivorship Working Group – Working Lunch

Co-Chairs: Heather Goltz, PhD, LMSW, MEd, University of Houston-Downtown and Nihal Mohamed, PhD, Mt. Sinai Icahn School of Medicine

1:00 – 2:30 **Breakout Sessions (page 6)**

About Breakout Sessions/Working Groups

The Think Tank offers *breakout sessions* each day to provide an opportunity for an in-depth discussion of timely topics across the bladder cancer spectrum. *Working groups*, which are scheduled at the same time as breakout sessions, meet annually at the Think Tank to study and report on a particular question and identify collaborative future projects. Think Tank attendees are welcome to join new and existing working groups.

Friday, August 9, 2019 Breakout Discussion Sessions and Working Groups

1. **Urinary Diversion**

Co-Chairs: Anne Schuckman, MD, Keck School of Medicine, USC, and Kamal Pohar, MD, The Ohio State University

This session will focus on common techniques of urinary reconstruction, appropriate patient selection, and management of complications. We will share and compare patient outcomes based on published literature and personal experiences focusing on patient-related outcomes. Our discussion will include patient goals with diversion and trends in diversion with both open and minimally invasive techniques.

2. **Tumor Microenvironment.**

Co-Chairs: Vivek Arora, MD, PhD, Washington University School of Medicine, St. Louis, and David J. DeGraff, PhD, Pennsylvania State University

The tumor microenvironment (TME) is closely connected to every step of tumorigenesis and progression. In addition, the TME can also strongly impact the efficacy of drug treatments. This session provides an overview of the spectrum of tumor microenvironment components in bladder cancer, as well as introduces cutting edge models and technologies for microenvironment studies. Time is planned for discussion focused on identifying opportunities for better defining the role of the tumor microenvironment in the bladder cancer progression and response to treatment.

3. **Patient Centered Outcomes Research and Policy (PCORP) Working Group**

Co-Chairs: John L. Gore, MD, MS, FACS, University of Washington and Seth Strobe, MD, MPH, Baptist MD Anderson Cancer Center

The PCORP working group is devoted to developing and implementing patient-centered outcomes research in bladder cancer. This session will discuss research projects being developed by the Patient-Centered Outcomes Research Institute (PCORI)-funded PEER Scholars program and future directions harnessing the BCAN Patient Survey Network and PEER programs. Join the engagement of patients, advocates, clinicians, and industry to help drive research efforts forward.

4. **Practical Considerations for Immunotherapy in Bladder Cancer.**

Co-Chairs: Arjun Balar, MD, NYU Langone Perlmutter Cancer Center, and Parminder Singh, MD, Mayo Clinic

This session is designed for care providers including urologists and oncologists to better understand the expanding role of immunotherapy in bladder cancer with particular focus on first-line metastatic and early stage/localized disease. We will also discuss strategies for diagnosing and managing immunotherapy toxicities in a multidisciplinary setting.

5. **Seeking Value in Bladder Cancer Care: An Assessment of Cost and Cost Containment Strategies.**

Ben Ristau, MD, MHA, University of Connecticut Health, and Matt Mossanen, MD, Brigham and Women's Hospital

Financial toxicity is becoming increasingly common for patients with cancer. Bladder cancer comprises a significant portion of the total spend on cancer care among

Medicare beneficiaries. This session will focus on both direct and indirect costs associated with bladder cancer management stratified by disease stage and ways in which these costs may be mitigated. Frank Sloan, PhD, J. Alexander McMahon, Professor of Health Policy and Management and Professor of Economics Emeritus at Duke University will join us to discuss his BCAN-funded research, quantifying the financial burden of bladder cancer in the Medicare population.

6. Women & Bladder Cancer – Gender Differences

Co-Chairs: Jean Hoffman-Censits, MD, Johns Hopkins Medicine and Sima Porten, MD, MPH, University of California San Francisco

Though more common in men, bladder cancer tends to have worse clinical behavior in women. While we know some information on the cause of this differential outcome, very little research is focused on gender disparity in bladder cancer. In this session, we will present an up-to-date overview of gender-based outcomes for patients with bladder cancer and discuss the state of current research. We will present a summary of the joint Spring 2019 JHH/AUA meeting on the topic and identify ongoing research questions in the basic, surgical, therapeutic, and supportive care realms. Discussions will include initiation of possible prospective multicenter patient-centered projects in this arena.

7. Novel Approaches in Management of NMIBC: Beyond BCG

Co-Chairs: Ashish Kamat, MD, MBBS, FACS, MD Anderson Cancer Center, and Josh Meeks, MD, PhD, Northwestern Medicine

This session will provide a detailed update of options for patients beyond BCG; specifically, what to do in times of BCG shortage, and what to do when BCG fails, including in active clinical trials. Our session will summarize emerging data relevant to clinical research efforts in the field. This multi-disciplinary discussion will focus on developing collaborative research efforts and resources for investigators seeking to develop projects to improve clinical care and research for NMIBC in collaboration with similar working groups in NMIBC.

8. Genomic Insights and Biomarkers for Treatment Selection in Muscle-Invasive and Non-Muscle-Invasive Bladder Cancer (NMIBC and MIBC)

Co-Chairs Yair Lotan, MD, UT Southwestern Medical Center and Alexandre Zlotta, MD, PhD, FRCSC, Mt Sinai Hospital, Toronto

There are important management decisions in patients with NMIBC and MIBC. Clinical information including stage, grade, and patient characteristics are insufficient in accurately predicting the behavior of bladder cancer. Considering this need for markers to assist with managing patients: Can urine markers actually offer prognostic information for NMIBC especially in setting of BCG treatment? What urine or tissue markers predict response to BCG? Can tumor markers (genetic information) predict non-organ confined disease in patients who are scheduled for cystectomy (cT1/cT2) or predict response to neoadjuvant chemotherapy? Our session will include discussion on the value of molecular markers to improve detection of high-grade disease or avoid cystoscopy in low-grade disease.

Saturday, August 10, 2019 Breakout Discussion Sessions and Working Groups

1. Bladder Preservation – Working Group

Co-Chairs: Christopher Anderson MD, Columbia University Irving Medical Center, and Jason Efstathiou, MD, DPhil, Massachusetts General Hospital.

Patients have long believed their best bladder is the one they were born with. This working group will address areas of progress and controversy in bladder preservation in MIBC, including topics such as cystectomy vs. bladder-sparing therapy, the role of surveillance following complete response to neoadjuvant chemotherapy, surgical considerations such as TURBT alone, partial cystectomy, and feasibility of constructing a neobladder at the time of salvage cystectomy. How do we improve outcomes in the elderly and in patients with variant histologies? What is the relevance of emerging data on checkpoint inhibitors for non-metastatic muscle invasive bladder cancer? Is there a role for chemotherapy alone in genetically favorable subgroups? We will also discuss emerging biomarkers of chemoradiotherapy response, as well as updates on cooperative group and institutional protocols.

2. Modeling UC in the Lab: One Size Doesn't Fit All...

Co-Chairs: Chong-Xian Pan, MD, PhD, UC Davis Health and Trinity Bivalacqua, MD, PhD, Johns Hopkins Medicine

This session will review various pre-clinical models of urothelial carcinoma, such as patient-derived xenografts, organoids, conditionally reprogrammed cell cultures, genetically engineered mouse models, carcinogen-based models and others. We will discuss the pros, cons, and potential clinical applications of these models and foster collaborations among clinicians and researchers working on urothelial cancer.

3. From Concept to Concrete - Actualizing Microbiome Studies in Bladder Cancer

Co-Chairs: Randy Sweis, MD, University of Chicago Medicine, and Molly Ingersoll, PhD, Institut Pasteur

The gut and bladder/urine microbiomes may influence response to immunotherapies including BCG and anti-PD-1/L1 therapy. This breakout session will discuss emerging data in bladder cancer and explore the technical and scientific challenges to studying microbiomes in translational research. One goal of this session is to refine our approach to investigating the microbiome in pre-clinical and clinical studies to develop synergistic collaborations among the bladder cancer community and related fields of microbiome science and bioinformatics to advance our knowledge of bladder cancer/therapy/microbiome interactions more rapidly.

4. Caregiving Research in Bladder Cancer

Co-Chairs: Sumeet Bhanvadia, MD, Keck School of Medicine, USC, and Renata Louwers, BCAN Patient Advocate

This session highlights the status of the field of caregiving research, and notes some major areas of study, methodological issues in caregiving research, understudied topics in the field, and sources for funding for caregiving research. Discussion will focus on bladder cancer caregiver outcomes, interventions to improve caregiver quality of life

and burden, and leveraging research opportunities to fill critical gaps in evidence with a goal of improving the quality of life for families and care recipients.

5. The Boots on the Ground Approach: Innovation in Clinical Trials Management.

Co-Chairs: Matthew Milowsky, MD, UNC Lineberger Comprehensive Cancer Center and Elizabeth Plimack, MD, MS, Fox Chase Cancer Center

Unravel the complexities of the clinical trials process through an interactive discussion among stakeholders including academia, industry, the FDA and patient advocacy. Topics will include a discussion of the importance of patient engagement in research and clinical trials processes from both an operational and regulatory standpoint. Building on discussions from last year, we invite research staff, patient advocates, and clinical investigators to discuss site-level innovative strategies that have worked well, and gather input from stakeholders in pharma to further facilitate advancing bladder cancer treatment through clinical investigation.

6. Upper Tract Urothelial Carcinoma (UTUC) Working Group

Co-Chairs : Jonathan Coleman, MD, Memorial Sloane Kettering Cancer Center and Jean Hoffman-Censits, MD, Johns Hopkins Medicine

The UTUC working group will provide a detailed update of currently active clinical trials, emerging data relevant to clinical research efforts in the field, and a venue for multi-disciplinary discussion focused on developing collaborative research efforts and resources. For investigators seeking to develop projects to improve clinical care and research for UTUC, this is not to be missed.

7. Patient-Driven Endpoints and Toxicity Thresholds in Non-Muscle Invasive Bladder Cancer (NMIBC) Working Group

Co-Chairs: Noah Hahn, MD, Johns Hopkins Medicine, Gary Steinberg, MD, FACS, NYU Langone, and Rick Bangs, BCAN Patient Advocate

With the recent approval of multiple immune checkpoint inhibitors in patients with metastatic disease and an improved understanding of relevant targetable genetic aberrations from the TCGA and other genomic investigations, clinical trials are rapidly moving promising systemic agents into testing in patients with NMIBC. While the FDA has provided initial guidance on efficacy endpoints for regulatory approval, a critical need exists to define additional clinically relevant endpoints and acceptable risk vs. benefit profiles of agents studied in the NMIBC population. To date, engagement of patients in this crucial dialogue has been modest. This working group aims to bring bladder cancer patients, their family members, and bladder cancer health care providers together to prospectively construct guidance on these important aspects of NMIBC clinical trial design with an emphasis on directly incorporating patients in this process. Our goal is to provide important patient driven data to the FDA to complement current NMIBC clinical trial design guidelines.