

2019 THINK TANK

PROGRAM GUIDE

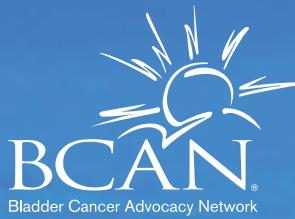
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Collaborating to
Move Research
Forward

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AUGUST 8-10, 2019

Capital Hilton
1001 16th Street, NW
Washington, DC 20036



August 6–8, 2020

The Westin Denver Downtown
1672 Lawrence Street
Denver, Colorado 80202



15TH ANNUAL

SAVE THE DATE

THINK TANK 2020

Thank You to the 2019 Think Tank Steering Committee

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University of California San Francisco

Karen Sachse, RN, BCAN Patient Advocate

Angela B. Smith, MD, MS, University of North Carolina School of Medicine

Robert Svatek, MD, University of Texas San Antonio

Dear Colleagues,

August 8, 2019

It is our great pleasure to welcome you to Washington, DC for the 2019 BCAN Think Tank. We look forward to engaging and productive discussions focused on improving the lives of patients affected by bladder cancer through research, clinical care, education, and advocacy.

Over the past decade, the BCAN Think Tank has become the premier meeting in North America focused on bladder cancer. The Think Tank has evolved over this time to progressively integrate a growing group of stakeholders involved in the care of patients with bladder cancer and to include all aspects of the patient and caregiver journey from diagnosis to treatment to survivorship. The Think Tank has become an incubator for new collaborations, projects, and grant submissions, a venue to share progress on existing projects, and a space to connect with new and old colleagues alike. If this is your first Think Tank, we are thrilled that you are joining our growing family and are bringing your unique perspective and skill set to bear on our collective mission, or if you are a return participant, we thank you for your presence and contribution.

Our program this year includes sessions focused on a diverse set of themes including palliative care, regulatory science, and computational biology along with a number of new as well as popular recurring breakout sessions.

Thanks to the Steering Committee, Session Chairs, and Breakout Session Leaders for creating an amazing program sure to be both stimulating and inspiring.

Enjoy the meeting,
—Sia and Matt



Sia Daneshmand
Program Chair



Matt Galsky
Program Co-Chair

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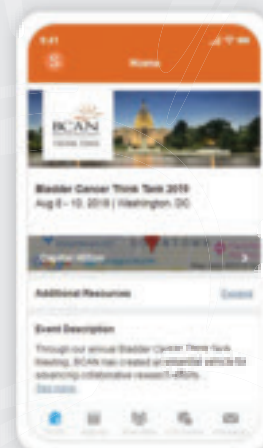


Things you can do:

- See who else is attending
- Introduce yourself
- Network with other attendees
- Send a tweet and share photos
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1. From the App Store on your phone or tablet, **DOWNLOAD** the WHOVA app
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SCHEDULE OF EVENTS

THURSDAY, AUGUST 8

- 10:00 – 12:00 Patient Advocacy Session (for patient advocates only)
- 12:00 – 4:00 FDA/CDER and BCAN Workshop “Endpoints for the Development of Neoadjuvant Systemic Therapy Regimens for Muscle-Invasive Bladder Cancer”
- 2:00 – 4:00 Think Tank Registration
- 4:00 – 5:00 **Opening Remarks and Introductions** | BCAN CEO Andrea Maddox-Smith, Co-Founder Diane Zipursky Quale and a special update on the “Bladder Cancer Genomics Consortium UC-Genome Project” from Matthew Milowsky, MD
- 5:00 – 6:00 **Rethinking Follow Up - Addressing Survivors Needs** | 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, and Robert Svatek, MD, University of Texas 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.
- Featuring:
- Lee Hugar, MD, MSCR, University of Pittsburgh
 - Terrence Friedlander, MD, University of California San Francisco
 - Leslie Ballas, MD, University of Southern California
 - Gary Winzelberg, MD, MPH, University of North Carolina
- 10:15 – 11:30 **2019 John Quale Travel Fellow Presentations**
- 11:30 – 12:45 **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: Andrea Apolo, MD, NIH, Seth P. Lerner, MD, FACS, Baylor College of Medicine, and Chana Weinstock, MD, FDA
- 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.

Featuring:

- Jamie Marko, MD, National Institutes of Health Clinical Center

3:00 – 3:30 Break

3:30 – 5:00 **Breakout Sessions | Please see [Appendix A](#)**

5:30-7:30 Happy Hour & John Quale Travel Fellows Poster Session - hosted by BCAN CEO, Andrea Maddox-Smith

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.

Featuring:

- Seungchan Kim, PhD, Prairie View A&M University
- Gordon Robertson, PhD, British Columbia Cancer Agency, Genome Sciences Centre
- Nikolaus (Nikki) Schultz, PhD, Memorial Sloan Kettering Cancer Center

10:15 – 11:30 **BCAN Young Investigator Award Research Presentations**

Tracy Rose, MD, MPH, University of North Carolina, Chapel Hill

Philip Abbosh, MD, PhD, Fox Chase Cancer Center

Eugene Lee, MD, University of Kansas Health System

David Oh, MD, PhD, University of California, San Francisco

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 | Please see [Appendix B](#)**

2:30 **Think Tank Adjourns**

1 | Urinary Diversion

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

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 Siteman Cancer Center, 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 Strope, MD, MPH, Urology of St. Louis

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 to answer patient-centered research questions in bladder cancer care. 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 Permuter 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

Co-chairs: Matthew Mossanen, MD, Brigham and Women's Hospital, and Ben T. Ristau, MD, MHA, University of Connecticut Health

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, the 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 and 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 University Feinberg School of 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.

ABOUT BREAKOUT SESSIONS/WORKING GROUPS

Think Tank offers breakout sessions each day to provide an opportunity for 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.

1 | Bladder Preservation – Working Group

Co-Chairs: Christopher B. 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 All6

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

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

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

Chair: Sumeet Bhanvadia, MD, Keck School of Medicine, USC

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 A. Coleman, MD, Memorial Sloan 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 D. Steinberg, MD, FACS, NY University Langone Health, and Rick Bangs, BCAN Patient Advocate

With the recent approval of immune checkpoint and FGFR 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.

CONGRATULATIONS TO THE 2019 JOHN QUALE TRAVEL FELLOWS

Since 2009, the John Quale Travel Fellowship Program has engaged early-career individuals interested in bladder cancer research, including basic scientists, urologists, oncologists, and pathologists by providing funding to defray travel related costs to attend the annual Bladder Cancer Think Tank. Be sure to visit their poster presentations during the CEO Happy Hour on Friday evening.



Lee Hugar, MD, University of Pittsburgh Medical Center

Mentors: Benjamin Davies, MD and Bruce Jacobs, MD, of University of Pittsburgh

"The recognition that I received from this award undoubtedly played an important part in cementing my role in the international bladder cancer research community, and fostered my success in securing external grant funding for my bladder cancer projects."

— Randy Sweis, MD, 2015 Quale Fellow



Amy Lim, MD, PhD, University of Texas MD Anderson Cancer Center

Mentors: Colin Dinney, MD and Neema Navai MD, MD Anderson Cancer Center



Samuel Washington, MD, University of California San Francisco

Mentors: Sima Porten, MD, MPH, Maxwell Meng, MD and Peter Carroll, MD, MPH, University of California San Francisco



Amy Luckenbaugh, MD, Vanderbilt University Medical Center

Mentors: Sam Chang, MD, MBA, David Penson, MD, MPH, NMHC, Vanderbilt University Medical Center



Nathan Wong, MD, FRCSC, Memorial Sloan Kettering Cancer Center

Mentors: Jonathan Coleman, MD and Gopa Iyer, MD, Memorial Sloan Kettering Cancer Center



Swathi Ramakrishnan, MD, Health Research Incorporated, Roswell Park Cancer Institute Division

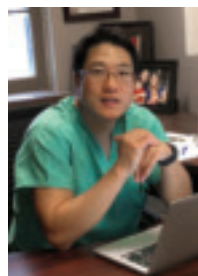
Mentors: Gurkamal Chatta, MD and Anna Woloszynska, PhD, Roswell Park Comprehensive Cancer Center

BCAN IS COMMITTED TO ADVANCING BLADDER CANCER RESEARCH

Supporting bladder cancer research has always been an integral part of BCAN's mission. BCAN's research grant program attracts "the best and the brightest" who are applying their talent, knowledge and experience to improving the understanding and treatment of bladder cancer. Presenting at the 2019 Think Tank:



The 2017 **Bladder Cancer Research Innovation Awardee** Seth P. Lerner, MD, FACS, for his project, "Proteogenomic characterization of muscle-invasive bladder cancer to identify mechanisms of resistance and targets for therapy."



The 2018 **Palm Beach New Discoveries Young Investigator Award for Patient-Centered Clinical Research Awardee** Eugene Lee, MD, for his proposal, "The implementation of nutrition education videos for patients undergoing radical cystectomy."



The 2017 **Stephen Hale Gushée Young Investigator Awardee** Tracy Rose, MD, MPH, Assistant Professor at UNC Chapel Hill, for her research, "Defining the Immune Response to Chemotherapy and Chemo-Immunotherapy in Muscle-Invasive Bladder Cancer."



The 2018 **Palm Beach New Discoveries Young Investigators Awardee** David Oh, MD, PhD, a Post-Doctoral Fellow at the University of California, San Francisco, for his proposal "Modulation of regulatory T cells in the bladder tumor environment by anti-PD-L1 immunotherapy."



The 2018 **BCAN Young Investigator Awardee** Philip Abbosh, MD, PhD, Assistant Professor, at Fox Chase Cancer Center, for his work on "Next-generation sequencing to enhance initial staging and dynamically monitor disease response in upper tract urothelial carcinoma (UTUC)."



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In 2018, Charity Navigator, an influential, independent evaluator of nonprofits, named BCAN as a "Top 10 U.S. Medical Research Organization" underscoring our commitment to use donors' funds effectively.

2019 Think Tank Speakers and Co-Chairs



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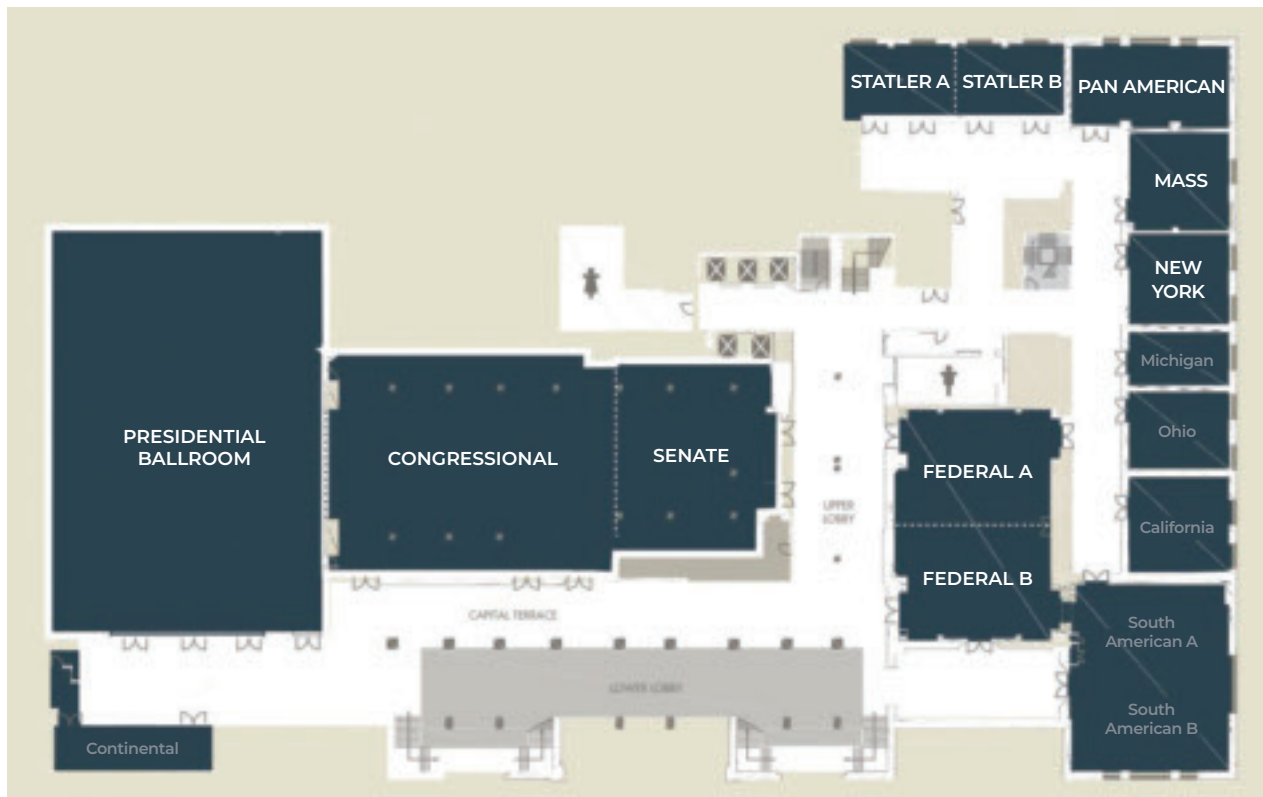
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CAPITAL HILTON - 2019 THINK TANK MEETING ROOMS

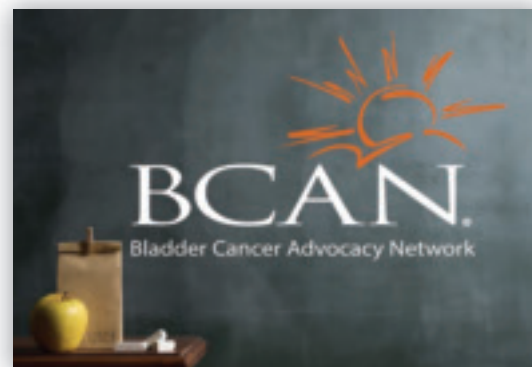


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Bladder Cancer Basics Handbook

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Do you remember when you wanted to change the world?

You still can—with a legacy gift in support of research to the Bladder Cancer Advocacy Network.

Contact us today to learn more about how you can help fund our mission to advance bladder cancer research and provide hope for all those coping with this disease. Our research program is leading to new life-saving discoveries as we support forward-thinking ideas and breakthrough treatments in the management of bladder cancer.

Anita Parker

Director of Planned Giving
301.215.9099 ext. 202
aparker@bcan.org

Do you want to make a significant gift that will transform the future of the Bladder Cancer Advocacy Network for generations to come?

You can do it today by:

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