



2018 Program Schedule

August 2-4, 2018 | Denver, CO

Collaborating to Move Research Forward

Thursday, August 2

- 10:00 – 1:00 Patient Advocacy Session (for patient advocates only)
- 2:00 – 4:00 Registration
- 4:00 – 5:00 Opening Remarks and Introductions
- 5:00 – 6:00 Keynote Address and Q&A | Joe Selby, MD, MPH
Executive Director, Patient-Centered Outcomes Research Institute

About Dr. Selby: A family physician, clinical epidemiologist, and health services researcher, Selby has more than 35 years of experience in patient care, research, and administration. He is responsible for identifying strategic issues and opportunities for the Patient Centered Outcomes Research Institute. Dr. Selby will address possibilities for conducting larger, simpler clinical trials (and observational studies) in oncology in real world settings using combinations of EMR, tumor registry, claims and self-report data – and randomization when necessary.

- 6:00 – 9:00 Founders Reception and Dinner

Friday, August 3

- 7:00 – 8:00 Breakfast
- 8:00 – 10:00 **Contributions of the Microbiome to Cancer and Bladder Disease**
Co-Chairs: Molly Ingersoll, PhD, Institut Pasteur and Randy Sweis, MD, University of Chicago

What is the role of gut and bladder biodiversity in the development and treatment of bladder cancer? This session will review emerging data from studies of the gut and bladder microbiomes. Experts provide an overview of the bladder microbiome and its impact on the health of the bladder, the role of specific commensal gut bacteria on modulating the response to immune checkpoint inhibition, and the potential role the bacterial microbiome may play in bladder cancer.

Featuring:

Romina Goldszmid, PhD, National Cancer Institute
Jennifer Wargo, MD, MD Anderson Cancer Center
David Nelson, PhD, University of Indiana
Alan Wolfe, PhD, Loyola University

10:00 – 10:30 The JPB Foundation Bladder Cancer Research Innovation Award -- “Targeting FGFR3 in muscle-invasive bladder cancer.” | David McConkey, PhD, Director, Johns Hopkins Greenberg Bladder Cancer Institute

10:30 – 10:45 Break

10:45 - 12:45 Breakout Sessions (See Appendix A)

12:45 – 1:45 Lunch

1:45– 3:45 **Solving the Clinical Trials Conundrum**

Co-Chairs: Matt Milowsky, MD, UNC Lineberger Comprehensive Cancer Center, and Matt Galsky, MD, Mt. Sinai School of Medicine

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.

Featuring:

Ariel Bourla, MD, PhD, Flatiron Health

Howard A. “Skip” Burris III, MD, FACP, FASCO, President Elect, ASCO

Jane Perlmutter, PhD, MBA, PCORI Advisory Panel on Patient Engagement

Chana Weinstock, MD, Medical Officer, Genitourinary Cancers Team, FDA

3:45 – 4:45 **2018 John Quale Travel Fellow Presentations**

5:30-7:00 Happy Hour hosted by BCAN CEO

Saturday, August 5

- 7:00 – 8:00 Breakfast
- 8:00 – 9:00 **BCAN Young Investigator Award Research Presentations:**
2017 Tracy Rose, MD, University of North Carolina Chapel Hill
Byron Lee, MD, Cleveland Clinic Foundation
2015 Rahul Parikh, MD, PhD, University of Kansas
- 9:00- 9:15 Break
- 9:15 – 11:15 Breakout Sessions (See Appendix B)
- 11:15 – 12:30 Lunch
- 12:30 – 2:30 **Upper Tract Urothelial Carcinoma (UTUC): From improvisation to research-driven care**
Co-Chairs: Vitaly Marguils, MD, University of Texas Southwestern Medical School, and Surena Matin, MD, MD Anderson Cancer Center
- The management of UTUC has largely relied on improvisation of care due to the scarcity of direct evidence and translated knowledge from bladder cancer. Universal point of care screening suggests a high rate of undiagnosed Lynch Syndrome in patients with UTUC, and little evidence exists to aid screening for those diagnosed with this inheritable disease. We highlight the growing interest in UTUC therapy, as witnessed by the first intergroup trial for UTUC in the USA evaluating neoadjuvant chemotherapy, and a European trial of adjuvant chemotherapy. Experts discuss the growing understanding of UTUC based on tumor mutational and expression profiling, identifying potential therapeutic strategies.
- Featuring:
Jonathan Coleman, MD, Memorial Slone Kettering Cancer Center
Jean Hoffman-Censits, MD, Johns Hopkins Greenberg Bladder Cancer Institute
Ajay Alva, MD, University of Michigan
- 2:30- 3:00 Closing Remarks

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.

1. Communication skills for collaborative decision-making - Workshop

Timothy Gilligan, MD, Cleveland Clinic, Chair

There is a strong trend in medicine toward recognizing the patient as a key member of the healthcare team. By helping patients play an active role in healthcare decision-making, we can help mitigate the sense of disempowerment that accompanies illness. This workshop will present and offer an opportunity to practice communication skills for engaging patients and colleagues in collaborative decision-making. This highly interactive workshop will focus on experiential learning and skills practice. The same workshop is offered Friday and Saturday.

2. Performance Measurement and Quality Improvement Initiatives

Benjamin T. Ristau, MD, MHA, University of Connecticut Health, and Marc Smaldone, MD, Fox Chase Cancer Center, Co-Chairs

Public reporting of healthcare quality is becoming increasingly common. Currently, few validated quality metrics for bladder cancer care exist. This breakout discussion will review the variables for measuring quality of bladder cancer care from administrative datasets; discuss potential platforms (e.g. physician-led quality collaboratives) for obtaining more granular data, and use principles of implementation science to disseminate high quality care.

3. Urinary Diversions in 2018

Eila Skinner, MD, Stanford University and Sia Daneshmand, MD, USC Norris Comprehensive Cancer Center, Co-Chairs

This breakout session will focus on some of the techniques of reconstruction, appropriate patient selection, and management of common complications. Patient outcomes based on published literature and personal experience focusing on patient related outcomes will be shared and compared. The management of various complications encountered with various forms of diversion is included.

4. Immune-related Adverse Events in Bladder Cancer (irAE) - Strategies and challenges in management, special populations, and future research directions

Matthew R. Zibelman, MD, Fox Chase Cancer Center and Jean Hoffman-Censits, MD, Johns Hopkins Greenberg Bladder Cancer Institute, Co-Chairs

Immunotherapy using immune checkpoint blockade has revolutionized systemic therapy options and improved bladder cancer patient outcomes. This introduces new challenges in diagnosing, managing, and understanding the spectrum of immune-related adverse events. Join the discussion as we review the diagnosis and management of various irAE's, with emphasis on emerging and rare toxicities. Explore strategies employed on institutional levels to confront these challenges that often cross and overlap medical specialties, and highlight the role of education for patients, staff, and providers. We will address the potential implications of these therapies as they are deployed in new settings, e.g., in patients with NMIBC, as adjuvant therapy, controversial "real-world" scenarios such as patients with underlying baseline autoimmunity, re-treatment after toxicity, poor PS, and hyper progression. Other open topics may include emerging biomarkers of toxicity and response, the association of adverse events and clinical benefit, and whether toxicity varies across drug and target.

5. **Molecular Classification and Targeted Therapy**

Peter H. O'Donnell, MD, University of Chicago and Shilpa Gupta, MD, University of Minnesota, Co-Chairs

Molecular characterization of urothelial tumors is becoming increasingly commonplace for patients with advanced disease. Not only has this practice allowed a better understanding of the genomic landscape and heterogeneity of urothelial cancers, but it has led to identification of new therapeutic targets. We will explore current molecular targets and related clinical studies of genomic “targeted therapies” in urothelial cancer.

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

Noah Hahn, MD, Johns Hopkins Greenberg Bladder Cancer Institute, Chair

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/benefit profiles of new agents studied in the NMIBC population. To date, engagement of patients in this crucial dialogue has been modest. This new 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. The ultimate goal of this working group is to provide important patient driven data to the FDA to complement current NMIBC clinical trial design guidelines.

7. **UTUC Working Group**

Vitaly Marguils, MD, University of Texas Southwestern Medical Center and Surena Matin, MD, MD Anderson, Co-Chairs

The working group on upper tract urothelial carcinoma will update current/upcoming clinical trials and provide a resource for investigators seeking to develop projects that aim to improve clinical care and research for UTUC.

8. **Survivorship Working Group**

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

Sharing survey data of bladder cancer patients in their lived environments and experience, this working group is developing patient-centered programs that improve quality of life and disease self-management for bladder cancer survivors, caregivers and family through education, research and advocacy.

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2. **The Boots on the Ground Approach to Solving the Clinical Trials Management Conundrum**

Elizabeth Plimack, MD, Fox Chase Cancer Center, Matt Milowsky, MD, UNC Lineberger Comprehensive Cancer Center, and Matt Galsky, MD, Mt. Sinai School of Medicine

Successful clinical research requires a complex infrastructure with expertise from many disciplines in the research team including nursing, data management, regulatory support, quality assurance, financial management, contracting, scientific and internal review board committees, and clinical investigators. At the same time, we are seeing a surge in the quantity of clinical trials and patient slots for such trials at a time when trial design is becoming increasingly complex. This session will include stakeholders from the *boots on the ground* to review the complexities of clinical trials and discuss potential solutions to streamline and improve processes.

3. **Palliative Care**

Mary Dunn, RN, MSN, OCN, NP-C, University of North Carolina School of Medicine, and Renata Louwers, BCAN Patient Advocate/Writer, Co-Chairs

Palliative care is a multidisciplinary approach that improves the quality of life of patients and families across the spectrum of an illness or disease. Discern the facts from the fiction concerning the unique palliative care needs of bladder cancer patients and caregivers. Tools to address these needs will be highlighted, and the discussion group will brainstorm the development of bladder cancer-specific palliative care resources.

4. **Is it Finally Time to Embrace Postoperative Intravesical Chemotherapy after TURBT?**

Yair Lotan, MD, UT Southwestern Medical Center, Dallas, Chair

New data is emerging from large randomized trials regarding postoperative intravesical chemotherapy after TURBT. Join the discussion of the role of this treatment in intermediate and high-risk patients and which agents may be best. With discussion leaders: Mike O'Donnell, MD, University of Iowa, and Edward Messing, MD, University of Rochester School of Medicine and Dentistry.

5. **The Next Enhancements in Enhanced Recovery: Taking ERAS into the Future**

Jay B. Shah, MD, Stanford University Medical Center and Sima Porten, MD, MPH, University of California San Francisco, Co-Chairs

Data support a continuum of pre-habilitation, ERAS, and rehabilitation to improve outcomes in patients undergoing cystectomy. Yet there are barriers to implementing these principles as routine patient care. This breakout discussion will identify a cohesive set of materials that can be used by providers interested in adopting a comprehensive enhanced recovery plan at their institutions. Help identify ways to overcome barriers and systematically study these programs to better risk assess, assign, and deliver a personalized perioperative care plan for each patient.

6. **Bladder Preservation – Current Status & Future Perspectives**

James McKiernan, MD, Columbia University Medical Center, and Jason Efstathiou, MD, DPhil, Massachusetts General Hospital, Co-Chairs

Patients have long believed their best bladder is the one they were born with. This session addresses areas of progress and controversy in bladder preservation, including topics such as cystectomy vs. bladder-sparing therapy, the role of neoadjuvant vs. adjuvant chemotherapy, surgical considerations such as TURBT alone and feasibility of constructing a neobladder at the time of salvage cystectomy. What is the response of CIS to chemoradiation? How do we improve outcomes in the elderly, and patients with variant histologies? Is there a role for chemotherapy alone in genetically favorable subgroups? We will discuss emerging biomarkers of chemoradiotherapy response, as well as updates on cooperative group and institutional protocols.

7. **Moving Beyond PD-1 Monotherapy: Rational Immuno-Oncology Combinations in Bladder Cancer**

Terence Friedlander, MD, University of California San Francisco, and Tracy Rose, MD, University of North Carolina Chapel Hill, Co-Chairs

PD-1 monotherapy has shown exciting activity and excellent tolerability in patients with metastatic bladder cancer, however only about 20% of patients have durable response. This interactive session will review the rationale for combining novel immunotherapies, describe ongoing studies, and discuss how to best design combination trials in the future.

8. **Patient Centered Outcomes Working Group**

John L. Gore, MD, MS, University of Washington and Seth Strobe, MD, Baptist Health, Co-Chairs

There is significant discussion about patient-reported outcomes (PRO) and research prioritization in the medical world today. This session will present the results of the Patient-Centered Outcomes Research Institute (PCORI) funded patient-centered research prioritization effort performed through BCAN. Join the engagement of patients, advocates, and clinicians to help drive this research prioritization effort forward.