Considerations for Harmonizing Clinical Trial Conduct in Adjuvant Bladder and Kidney Cancer: Inclusion Criteria and Disease Recurrence

Organized by the U.S. Food & Drug Administration (FDA) and National Cancer Institute (NCI)
with support from the Society of Urologic Oncology (SUO)
November 28, 2017 - 8:00 am – 5:00 pm
NIH Campus, Building 45, Room E1/E2
Twitter: #OCEGU17

8:00-8:05	**Welcome and Introduction – Andrea Apolo, M.D. – NCI and Harpreet Singh, M.D. - FDA**
8:05-8:15	**Workshop Rationale – Sundeep Agrawal, M.D. – FDA** Goals and Objectives • Discuss inclusion and eligibility criteria for adjuvant bladder and kidney cancer trials • Discuss considerations in defining and managing disease recurrence on adjuvant bladder and kidney cancer trials • Review common goals and methods for clinical trial conduct
8:15-9:30	**Harmonizing Inclusion Criteria Across Adjuvant Bladder Cancer Trials: Disease Characteristics and Surgical Considerations** **Moderators: Andrea Apolo, M.D. – National Cancer Institute and Ashish Kamat, M.D. – MD Anderson Cancer Center** • Disease and Patient Characteristics and Prior Neoadjuvant Therapy Matt Milowsky, M.D. – UNC Lineberger Comprehensive Cancer Center • Surgical Considerations Gary Steinberg, M.D. – University of Chicago Medical Center • Panel: Matt Milowsky, M.D. – UNC Lineberger Comprehensive Cancer Center Gary Steinberg, M.D. – University of Chicago Medical Center Rick Bangs – Patient Advocate Shenghui Tang, PhD. – FDA Dan Suzman, M.D. – FDA
9:30-9:45	**Break**
9:45-11:15	**Defining Radiographic Eligibility and Disease Recurrence on Adjuvant Bladder Cancer Trials: Strategies and Challenges** **Moderators: Dean Bajorin, M.D. – Memorial Sloan Kettering Cancer Center and Colin Dinney, M.D. – MD Anderson Cancer Center** • Radiographic Modalities and Procedures, Baseline and Surveillance Imaging, and

	the Role of Biopsy in Determining Recurrence Jonathan Rosenberg, M.D. - Memorial Sloan Kettering Cancer Center • From a Radiologist Perspective: Lauren Kim, M.D. – National Cancer Institute • Panel: Ashish Kamat, M.D. – MD Anderson Cancer Center Jonathan Rosenberg, M.D. – Memorial Sloan Kettering Cancer Center Sundeep Agrawal, M.D. - FDA Andrea Apolo, M.D. – National Cancer Institute Lauren Kim, M.D. – National Cancer Institute Rick Bangs – Patient Advocate
11:15-12:00	**Management of Non-Muscle Invasive Disease on Adjuvant Bladder Cancer Trials** **Moderators: Seth Lerner, M.D. – Baylor College of Medicine and Matt Milowsky, M.D. – UNC Lineberger Cancer Center** • Current Views on Managing NMIBC in Patients on Study Brant Inman, M.D. – Duke University Medical Center • Panel: Andrea Apolo, M.D. – National Cancer Institute Brant Inman, M.D. – Duke University Medical Center Gary Steinberg, M.D. – University of Chicago Medical Center Max Ning, M.D. - FDA Rick Bangs – Patient Advocate Colin Dinney – MD Anderson Cancer Center
12:00-12:45	**Lunch**
12:45-2:00	**Harmonizing Inclusion Criteria Across Adjuvant RCC trials: Disease Characteristics, Surgical Considerations, and Exploration of Biomarker Driven Trials** **Moderators: Chana Weinstock, M.D. – FDA and Jonathan Coleman, M.D. – Memorial Sloan Kettering Cancer Center** • Surgical and Other Considerations for Including Patients on Trial Robert Uzzo, M.D. – Fox Chase Cancer Center • Disease and Patient Characteristics for Adjuvant RCC Trials Naomi Haas, M.D. – University of Pennsylvania Hospital • Panel: Julia Beaver, M.D. – FDA Cynthia Chauhan – Patient Advocate Robert Uzzo, M.D. – Fox Chase Cancer Center Naomi Haas, M.D. – University of Pennsylvania Hospital Hans Hammers, M.D. – UT Southwestern Medical Center Jason Schroeder, Ph.D. – FDA Elizabeth Plimack, M.D. – Fox Chase Cancer Center

	Toni Choueiri, M.D. – Dana Farber
2:00-2:15	**Break**
2:15-3:45	**Defining Radiographic Eligibility and Disease Recurrence on Adjuvant Renal Cell Cancer Trials: Strategies and Challenges** **Moderators: Gennady Bratslavsky, M.D. – Upstate University Hospital and Sundeep Agrawal, M.D. - FDA** • Radiographic Modalities and Procedures, Baseline and Surveillance Imaging, and the Role of Biopsy in Determining Recurrence Hans Hammers, M.D. – UT Southwestern Medical Center • From a Radiologist Perspective: Mohammad Hadi Bagheri, M.D. – National Cancer Institute • Panel: Amna Ibrahim, M.D. – FDA Cynthia Chauhan – Patient Advocate Brian Lane, M.D. – Spectrum Health Hans Hammers, M.D. – UT Southwestern Medical Center Mohammad Hadi Bagheri, M.D. – National Cancer Institute Jonathan Coleman, M.D. – Memorial Sloan Kettering Cancer Center Toni Choueiri, M.D. – Dana Farber
3:45-4:15	**Public Comments and Question & Answer Session** • Panel: Andrea Apolo, M.D. – National Cancer Institute Harpreet Singh, M.D. - FDA Rick Bangs – Patient Advocate Cynthia Chauhan – Patient Advocate Naomi Haas, M.D. – University of Pennsylvania Dean Bajorin, M.D. – Memorial Sloan Kettering Cancer Center
4:15-5:00	**Workshop Summary and Conclusions – Harpreet Singh, M.D.** **Panel: All Moderators** • Review of key findings from each session • Plan and prioritize the next steps