

U.S. Food and Drug Administration (FDA) Workshop: Clinical Trial Design for Non-Muscle Invasive Bladder Cancer (NMIBC)

November 18 (9 am – 1 pm ET) and November 19 (9 am – 12 pm ET)

AGENDA		
Day 1: November 18, 2021 (9:00 am – 1:00 pm ET)		
BCG Shortage, Trial Design for BCG-Naïve Patients, Risk Stratification and Definition of Disease States, Bladder-Intact and High-Grade Event-Free Survival		
Welcome and Introduction	Elaine Chang	09:00-09:15
Session 1		
BCG Shortage: The Practice Environment (15 mins)	Seth Lerner	09:15-09:30
BCG Shortage: Strains of BCG (15 mins)	Robert Svatek	09:30-09:45
Panel Discussion: BCG Shortage (35 mins)	Moderator: Chana Weinstock Panelists: Peter Bross, Max Kates, Karen Sachse, Neal Shore, Seth Lerner, Robert Svatek	09:45-10:20
Break (10 mins)		10:20-10:30
Session 2		
BCG-Naïve Setting (15 mins)	Noah Hahn	10:30-10:45
Panel Discussion: Trial Design for the BCG-Naïve Setting (35 mins)	Moderator: Adnan Jaigirdar Panelists: Erik Bloomquist, Jamie Brewer, Michael O'Donnell, Gary Steinberg, Seth Lerner, Noah Hahn	10:45-11:20
Break (10 mins)		11:20-11:30
Session 3		
Risk Stratification, BCG-Unresponsive and Definitions of Disease States (15 mins)	Ashish Kamat	11:30-11:45
Cystectomy: Clinical Context (10 mins)	Maria Ribal	11:45-11:55
Cystectomy-Free Survival (15 mins)	Paul Kluetz	11:55-12:10
Panel Discussion: BCG-Unresponsive and Definition of Disease States, Cystectomy-Free Survival (45 mins)	Moderator: Charles Viviano Panelists: Matthew Galsky, Rick Oliver, Ashish Kamat, Paul Kluetz, Maria Ribal	12:10-12:55
Wrap-up of Day 1 (5 mins)	Jaleh Fallah	12:55-1:00

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AGENDA		
Day 2: November 19, 2021 (9:00 am-12:00 pm ET)		
Carcinoma In Situ (CIS), Papillary, and Patient-Focused Drug Development		
Welcome and Recap Day 1 (10 mins)	Chana Weinstock	09:00-09:05
Session 4		
Regulatory Considerations for Trial Designs in BCG-Unresponsive CIS (10 mins)	Sundeep Agrawal	09:05-09:15
Assessing CIS (10 mins)	Peter Black	09:15-09:25
CIS Pathology (5 mins)	Hikmat Al-Ahmadie	09:25-09:30
Panel Discussion (CIS) (30 mins)	Moderator: Jaleh Fallah Panelists: Kamal Pohar, Sundeep Agrawal, Hikmat Al-Ahmadie, Peter Black	09:30-10:00
Break		10:00-10:10
Session 5		
Pathways for Papillary Ta/T1 Disease (15 mins)	Colin Dinney	10:10-10:25
Trial Simulations (10 mins)	Zhou Feng	10:25- 10:35
Panel Discussion: Trial Design for Papillary Ta/T1 NMIBC (30 mins)	Moderator: Noah Hahn Panelists: Tracy Downs, Sima Porten, Seth Lerner, Colin Dinney, Zhou Feng	10:35-11:05
Break		11:05-11:10
Session 6		
Patient-Focused Drug Development: Capturing High-Quality Patient Experience Data (15 mins)	Angela Smith	11:10-11:25
Panel Discussion: Patient-Focused Drug Development and Patient-Reported Outcomes (30 mins)	Moderator: Neeraj Agarwal Panelists: Rick Bangs, Vishal Bhatnagar, Ken Brothers, Sarah Psutka, Angela Smith	11:25-11:55
Wrap-up and Next Steps	Elaine Chang	11:55-12:00