

**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)

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

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<b>AGENDA</b>		
<b>Day 2: November 19, 2021 (9:00 am-12:00 pm ET)</b>		
<b>Carcinoma In Situ (CIS), Papillary, and Patient-Focused Drug Development</b>		
<b>Welcome and Recap Day 1</b> (10 mins)	Chana Weinstock	09:00-09:10
<b>Session 4</b>		
<b>What is Success for CIS?</b> (20 mins)	Sundeep Agrawal Peter Black Hikmat Al-Ahmadie	09:10-09:30
<b>Panel Discussion (CIS)</b> (30 mins)	Moderator: Jaleh Fallah Panelists: Sundeep Agrawal, Peter Black, Hikmat Al-Ahmadie, Kamal Pohar	09:30-10:00
<b>Break</b>		10:00-10:10
<b>Session 5</b>		
<b>Pathways for Papillary Ta/T1 Disease</b> (25 mins)	Colin Dinney Zhou Feng	10:10-10:35
<b>Panel Discussion: Papillary</b> (30 mins)	Moderator: Noah Hahn Panelists: Zhou Feng, Seth Lerner, Sima Porten, Colin Dinney, Tracy Downs	10:35-11:05
<b>Break</b>		11:05-11:10
<b>Session 6</b>		
<b>Patient-Focused Drug Development: Capturing High-Quality Patient Experience Data</b> (15 mins)	Angela Smith	11:10-11:25
<b>Panel Discussion: Patient-Focused Drug Development and Patient-Reported Outcomes</b> (30 mins)	Moderator: Neeraj Agarwal Panelists: Angela Smith, Sarah Psutka, Rick Bangs, Vishal Bhatnagar, Ken Brothers	11:25-11:55
<b>Wrap-up and Next Steps</b>	Elaine Chang	11:55-12:00