U.S. Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Oncology Center of Excellence (OCE)
Office of Oncologic Diseases (OOD)
Division of Oncology 1 (DO1)

Contemporary Issues in Non-Muscle Invasive Bladder Cancer (NMIBC)
Trial Design and Interpretation
Hybrid Public Workshop
May 18, 2026 | 12:30 PM to 4:30 PM ET

Agenda

12:30-12:45 pm	**Welcome and Introduction** *Dan Suzman, MD* *Deputy Division Director, DO1, OOD, CDER, FDA*
12:45-1:00 pm	**Molecular Biological Similarities of CIS and Papillary NMIBC** *David McConkey, PhD* *University of Rochester Medical Center*
1:00-1:15 pm	**Clinical Similarities and Differences of CIS and Papillary NMIBC** *Seth Lerner, MD, FACS* *Baylor College of Medicine*
1:15-2:55 pm	**Panel Discussion: Similarities and Differences of CIS and Papillary NMIBC** *Moderator: Chana Weinstock, MD* *Clinical Team Leader, DO1, OOD, CDER, FDA* Discussion points: 1. Discuss your thoughts on the molecular and pathologic similarities and differences between CIS and papillary disease. Do you consider any differences to be meaningful from a clinical perspective (e.g. in terms of response to treatment with various mechanisms of action, risk of recurrence or progression)? 2. Discuss the likelihood of misdiagnosis of papillary-only disease (i.e. missed detection of concomitant CIS). 3. Discuss how you currently treat patients with papillary-only NMIBC in the BCG-unresponsive setting. What data or treatment guidelines have you relied on to make that treatment decision? How do you present your thought process behind this decision to patients?
2:55-3:10 pm	**~Break~**
3:10-3:25 pm	**BCG Substrain Non-Equivalence – A Chemistry, Manufacturing, and Controls (CMC) Perspective** *Joy Ghosh, PhD* *Microbiologist, Center for Biologics Evaluation and Research (CBER), FDA*
3:25-3:40 pm	**BCG Shortage – A Clinical Perspective** *Max Kates, MD* *Johns Hopkins University School of Medicine*
3:40-4:25 pm	**Panel Discussion: Current State of the BCG shortage and Implications for Clinical Trial Design** *Moderator*: *Brian Heiss, MD* *Clinical Reviewer, DO1, OOD, CDER, FDA* Discussion points: 1. How has the BCG shortage affected your practice? Both in terms of your own ability to treat patients and also in referral patterns from other practices? 2. Has your access to BCG improved or worsened for your patients compared to previous times, e.g. 1 year ago, or 5 years ago? 3. How, in your opinion, has the BCG shortage affected trial enrollment and trial conduct? 4. What alternatives to BCG are you currently using and in which clinical scenarios? Are there patients in certain clinical scenarios whom you would consider treating if BCG were abundantly available whom you are not treating now, given the shortage?
4:25-4:30 pm	**Concluding Remarks** *Chana Weinstock, MD* *Clinical Team Leader, DO1, OOD, CDER, FDA*