Discussion Question

What is a clinically meaningful complete response rate and duration of response in BCG-unresponsive CIS?

- From the 2013 workshop: Complete response (CR) rate of 40-50% at 6 months and a durable response of at least 30% for 18-24 months with the lower bound of the 95% confidence interval excluding 20% was thought to be clinically meaningful.

Audience members, please share your thoughts by typing in chat.
FDA Guidance states that “If effective therapies become available in BCG-unresponsive NMIBC, a randomized trial may be appropriate”

• Are there effective medical therapies available that could serve as a control arm? What would those therapies be?
Discussion Question
(Respond in chat)

What measures should be in place to minimize investigator bias in cystoscopic evaluation?