



**FDA Public Workshop
Clinical Trial Design Issues – Development of
New Therapies for
Non-Muscle Invasive Bladder Cancer
May 6, 2013**

**Manchester Grand Hyatt - San Diego, CA
Douglas Pavilion C & D**

Co-sponsored by the U.S. Food and Drug Administration (FDA) & the American Urological Association (AUA)

Co-Chairs: Jonathan Jarow, MD and Seth P. Lerner, MD, FACS

AGENDA

1:00	Introduction	Jonathan Jarow, MD
1:05	Regulatory Basis for U.S. Drug & Biologics Approval	Paul G. Kleutz, MD
1:20	Statistical Considerations in Designing Randomized Clinical Trials	Rajeshwari Sridhara, PhD
1:35	Are the current data that we have regarding BCG efficacy of good enough quality to establish a non-inferiority margin for trials today?	Seth P. Lerner, MD, FACS
1:50	Clarification Questions to Speakers	
2:00	Panel Discussion	Panel Members
3:00	<i>Break</i>	
3:15	Panel Discussion	Panel Members
5:00	Adjournment	