

**FDA/ UMD CERSI Pediatric Inflammatory Bowel Disease Drug Development Workshop**  
**November 16, 2018**  
**DRAFT Agenda**

<b>Session 1: Introduction</b>	
08:00- 08:10	<b>Opening Remarks</b> Jessica Lee, MD
08:10-08:30	<b>Regulatory Landscape</b> Mona Khurana, MD
08:30-08:45	<b>Epidemiology of Pediatric IBD (1)</b> Eric Benchimol, MD
08:45 – 09:00	<b>Epidemiology of Pediatric IBD (2) (Data from ImproveCareNow Registry)</b> Richard Colletti, MD and Michael Kappelman, MD
<b>Session 2: Dose Selection</b>	
09:00 – 09:20	<b>Introduction to Dose Selection from FDA Perspective</b> Dilara Jappar, PhD
09:20-09:35	<b>Regulatory Perspective on Dose Selection</b> Anand Balakrishnan, PhD
09:35-09:50	<b>Case Study: Industry Perspective</b> Arnab Mukherjee, PhD (Pfizer)
09:50-10:10	<b>Exposure Response in Pediatric IBD: Clinician Perspective</b> Marla Dubinsky, MD
10:10-10:25	<b>Break</b>
10:25-11:45	<b>Panel Discussion and Q/A</b> Moderators: Shirley Seo, PhD and Lily Mulugeta, PharmD
11:45-12:30	<b>Lunch</b>
<b>Session 3: Trial Design Considerations</b>	
12:30-12:45	<b>Regulatory Perspective on IBD Trial Design</b> Tara Altepeter, MD
12:45-1:05	<b>Innovative Trial Design for Rare Diseases</b> Margaret Gamalo-Siebers, PhD
1:05-1:20	<b>Use of Exposure-Response Information to Establish Efficacy in Pediatric Patients</b> Marc Gastonguay, PhD
1:20-1:35	<b>Case Study: Industry Perspective</b> Nael Mostafa, PhD (Abbvie)
1:35-2:25	<b>Panel Discussion and Q/A</b> Moderators: Juli Tomaino, MD and Laurie Conklin, MD
2:25-2:35	<b>Break</b>
<b>Session 4: Trial Conduct</b>	
2:35-2:50	<b>Enrolling Adolescents into Adult Trials</b> Bruce Sands, MD
2:50-3:05	<b>Lessons Learned in Conducting Pediatric IBD Trials: Industry Perspective</b> Anne Robinson, PharmD (Abbvie)
3:05-3:20	<b>Case Studies From Other Disease States</b> Yodit Belew, MD
3:20-3:35	<b>Patient Perspective – Crohn’s &amp; Colitis Foundation</b> Caren Heller, MD
3:35-4:40	<b>Panel Discussion and Q/A</b> Moderators: Ed deZoeten, MD and Jessica Lee, MD
4:40-5:00	<b>Changing the Paradigm: Removing Barriers, Building Bridges</b> Jeffrey Hyams, MD