FDA/UMD CERSI pJIA Drug Development Workshop
October 2nd, 2019
FDA White Oak, Great Room
DRAFT Agenda

Introduction	
8-8:05	**Opening Remarks (5 min)** Nikolay Nikolov, MD
8:05-8:20	**Regulatory Landscape (15 min)** Carolyn Yancey, MD
8:20-8:30	**Scientific Necessity in the Context of Extrapolation of Adult Efficacy Data to Pediatric Patients (10 min)** Skip Nelson, MD
Session 1: Disease Similarity RA/pJIA	
8:30-8:45	**Epidemiology and Natural History of pJIA (15 min)** Robert A Colbert, MD (NIH)
8:45-9:00	**Similarities and Differences between RA and pJIA (15min)** Peter Nigrovic, MD
9:00-9:15	**Treatment Paradigm and Armamentarium of Products used in pJIA (15 min)** Dan Lovell, MD
9:15-9:45	**Panel Discussion and Q/A (30 min)** **Panelists**: Carolyn Yancey, Robert A Colbert (NIH), Jay Mehta, Peter Nigrovic, Ricardo Suehiro, Skip Nelson **Moderators:** Rachel Glaser, MD (FDA) and TBD
9:45-10:00am BREAK	
Session 2: Dose Selection and Role of Modeling and Simulation	
10:00-10:15	**Regulatory Perspective on Dose Selection (15 min)** Renu Singh, PhD (FDA)
10:15-10:30	**Case Study 1: Industry Perspective (15 min)** Nael Mostafa, PhD (AbbVie)
10:30-10:50	**Use of Exposure-Response Information in Pediatric Drug Development (20 min)** Marc Gastonguay, PhD (Metrum Research Group)
10:50-11:30	**Panel Discussion and Q/A (40 min)** **Panelists:** Nikolay Nikolov**,** Nael Mostafa, Mara Becker, April Bingham, Suzette Peng, Vikram Sinha, Chandrahas Sahajwalla, Yaning Wang **Moderators:** Lily Mulugeta and Marc Gastonguay
11:30-12:30 LUNCH	
Session 3: Trial Design Considerations	

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12:30-12:50	**Landscape of pJIA Drug Development: Regulatory Perspective (20 min)** Jianmeng Chen, PhD (FDA) Summary of clinical programs submitted and reviewed by FDA
12:50-1:10	**Two Phase 3 trials of Remicade and Simponi in patients with Juvenile Idiopathic arthritis: Lessons Learned (20 min)** TBD (J&J)
1:10-1:25	**Industry Perspective on Enrollment Difficulties in Pediatric Trials (15 min)** TBD
1:25-2:00	**Alternative Approaches and Trial Design:** 1. **Bayesian Borrowing of Data (adult/historical), Active Control Trials, (20 min)** Rebecca Rothwell, PhD (FDA) 2. **Enrolling Pediatric Patients into Adult Trials (15 min)** Lisa Imundo, MD
2:00-2:15 BREAK	
2:15-3:45	**Panel Discussion and Q/A (1.5 hrs)** **Panelists:** Nikolay Nikolov, Rebecca Rothwell, Dawn Territo, Ricardo Suehiro, Laura Schanberg, Hermine Bruner, patient representative (TBD), Issam Zineh Moderators: Lynne Yao, MD (FDA) and Lisa Rider, MD (NIH)
3:45-4:05 4:05-4:15	**Summary Remarks (20 min) TBD** **Closing Remarks (10 min)** Nikolay Nikolov, MD