SCEPTER II Meeting
Clinical Trials to Evaluate Safety Outcomes in Procedural Sedation
November 17 – 19, 2016
Sofitel Washington DC Lafayette Square

Agenda

Thursday, November 17, 2016		
7:00 – 9:00 PM	*Welcome Dinner*	
Friday, November 18, 2016		
7:30 – 8:00 AM	*Continental Breakfast & Introductions*	Bob Dworkin, Dennis Turk, Denham Ward & Leah Crisafi
8:00 – 8:20 AM	Overview of Results of SCEPTER Efficacy Meeting	Mark Williams
8:20 – 8:30 AM	Q&A	
8:30 – 8:45 AM	MedDRA and Reporting of Adverse Events	Anna Zhao-Wong
8:45 – 9:00 AM	Quebec Guidelines for Reporting Pediatric Sedation	Maala Bhatt
9:00 – 9:30 AM	World SIVA Adverse Event Reporting Tool and Database	Keira Mason & Steve Green
9:30 – 10:00 AM	Q&A and Panel Discussion	Chair: Pratik Pandharipande
10:00 – 10:30 AM	*Break*	
10:30 – 11:00 AM	Common and Important Adverse Events in Adult Sedation	Pratik Pandharipande
11:00 – 11:30 AM	Common and Important Adverse Events in Pediatric Sedation	Joe Cravero
11:30 – 11:45 AM	Common and Important Adverse Events in Dental Sedation	Raymond Dionne

11:45 AM – 12:15 PM	Q & A and Panel Discussion	Chair: Randall Clark
12:15 – 1:15 PM	*Lunch*	
1:15 – 1:45 PM	Evaluating Safety and Adverse Events in Adult and Pediatric Procedural Sedation Clinical Trials: A Regulatory Perspective	Leah Crisafi
1:45 – 2:15 PM	Design of Clinical Trials to Detect Important Adverse Events	Dan Sessler
2:15 – 2:45 PM	Statistical Considerations for the Detection and Analysis of Rare Events	Bo Li
2:45 – 3:15 PM	Q & A and Panel Discussion	Chair: Franklin Dexter
3:15 – 3:45 PM	*Break*	
3:45 – 4:45 PM	Panel Discussion on Regulatory and Practical Perspectives of Adult and Pediatric Procedural Sedation Clinical Trials	Hannah Wunsch, Joe Cravero, Leah Crisafi, Franklin Dexter, Dan Sessler, Randall Clark, Eugenio Andraca-Carrera
7:00 – 9:00 PM	*Dinner*	
Saturday, November 19, 2016		
7:30 – 8:00 AM	Continental Breakfast	
8:00 – 8:30 AM	Literature Review of Adverse Events in Procedural Sedation	Mark Williams & Denham Ward
8:30 – 8:45 AM	Q&A	
8:45 – 9:45 AM	Group Discussion: Adverse Events by Organ System - What and How to Measure? • Respiratory	Denham Ward
9:45 – 10:15 AM	*Break*	

10:15 – 11:15 AM	Group Discussion: Adverse Events by Organ System - What and How to Measure?	
	• Gastro-intestinal	TJ Gan
	• Cardiovascular	John Berkenbosch
	• Neurological (including recovery profile and need for GA)	John Miner
	• Liver / Kidney / Muscle	David Gozal
11:15 – 11:30 AM	How to Report on the Efficacy of Interventions to Prevent Adverse Events	Albert Dahan
11:30 AM – 12:00 Noon	Q&A and Panel Discussion	Chair: Jenifer Lightdale
12:00 – 1:00 PM	*Lunch*	
1:00 – 2:00 PM	Panel Discussion: (1) Defining the Risk Level, What is Minor, Serious, etc? (2) Patient Selection for Clinical Trials (e.g., include patients at higher risk for adverse events)? (3) Phase 1 Trials? (4) "Stress" Testing in Clinical Trials?	Albert Dahan, Denham Ward, TJ Gan, John Berkenbosch, James Miner, David Gozal
2:00 – 2:30 PM	*Break*	
2:30 – 3:30 PM	Group Discussion: What is an Adverse Event in a Sedation Clinical Trial?	Chairs: Keira Mason, Steve Green
3:30 – 4:00 PM	Group Discussion: SCEPTER Next Steps	Chairs: Bob Dworkin, Denham Ward