

Measures of Outcome for Stimulant Trials (MOST)

March 25-26, 2015 Hilton Rockville Hotel and Executive Meeting Center Rockville, MD

The goals of this conference are to:

- 1. Review work that has been conducted validating outcome measures for clinical trials of stimulant use disorders;
 2. Review related target substances that have successfully developed clinically meaningful
- outcome measures for substance use disorders; and
- 3. Identify a research agenda for the development of a tool and related outcome measures that would be clinically meaningful for stimulant use disorder clinical trials.

Note: Slide presentations are available on the website for those presenters whose names are highlighted in red font.

Wednesday, March 25, 2015

7:30 – 8:30	Continental breakfast	
8:30 – 8:45	Welcome and introductions Goals of meeting	Eric C. Strain
8:45 – 9:15	Approach to outcome measure development or selection: A regulatory perspective	Ashley Slagle (FDA's Study Endpoints Group)
9:15 – 9:45	Experience in developing a tool using the CSSA as a model	Kyle Kampman
9:45 – 10:00	Discussant	
10:00 – 10:15	Q+A, group discussion	
10:15 – 10:30	Break	
10:30 – 11:00	An overview to the experience in developing an outcome for alcohol studies	Raye Litten
11:00 – 11:15	Discussant	Dan Falk
11:15 – 11:30	Q+A, group discussion	
11:30 – 12:00	The conundrum of changes in use versus abstinence as endpoints	Kathleen Carroll
12:00 – 12:15	Discussant	Celia Winchell
12:15 – 12:30	Q+A, group discussion	

12:30 – 1:30	Lunch			
1:30 – 3:00	Prior and on-going efforts to evaluate clinical benefit in stimulant trials, based upon past studies	Moderator: David McCann		
	Presenters (15 min each):			
	George Woody Brian Kiluk Shengan Lai Ivan Montoya			
	Discussant (15 min)	Phil Skolnick		
	Q+A, group discussion (15 min)			
3:00 – 3:15	Break			
3:15 – 3:45	Lessons learned from other addictions trials	Rachel Skeete		
3:45 – 4:00	Q+A, group discussion			
4:00 – 4:30	What research is needed? Wrap up for day	Eric C. Strain		
Thursday, March 26,	2015			
7:30 – 8:30	Continental breakfast			
8:30 – 10:15	Identifying an endpoint that would be persuasive for reimbursement	Moderator: Ivan Montoya		
	Presenters (15 min each; 15 min break in between):			
	Rhonda J. Robinson Beale Keith Isenberg Amy Duhig Connie Weisner			
	Discussant (15 min)	Elliot Ehrich		
	Q+A, group discussion (15 min)			
10:15 – 10:30	Break			
10:30 – 11:00	Practicalities of conducting biological assessments for drug use [different methods, frequency of testing]	Kenzie Preston		
11:00 – 11:15	Discussant	Celia Winchell		
11:15 – 11:30	Q+A, group discussion			
11:30 – 12:00	Summary of the meeting and next steps Eric Strain			