INITIATIVE ON METHODS, MEASUREMENT, AND PAIN ASSESSMENT IN CLINICAL TRIALS

IMMPACT-XII

"OUTCOME MEASURES FOR HUMAN EXPERIMENTAL AND CLINICAL STUDIES OF THE ABUSE LIABILITY OF ANALGESIC MEDICATIONS"

OCTOBER 1-2, 2009
HILTON ROCKVILLE
ROCKVILLE, MARYLAND

WEDNESDAY, SEPTEMBER 30

7:00 PM **RECEPTION AND DINNER**
at the Hilton

THURSDAY, OCTOBER 1

7:00–7:45 AM **CONTINENTAL BREAKFAST**

7:45–8:10 AM **Welcome, introductions, and IMMPACT update**
- Dennis Turk, PhD

8:10–8:20 AM **Meeting objectives and deliverables**
- Sandra Comer, PhD and James Zacny, PhD

8:20–8:40 AM **General considerations in developing and evaluating outcome measures of abuse liability**
- Laurie Burke, RPh, MPH

8:40–9:00 AM **A historical perspective on human abuse liability studies**
- Donald Jasinski, MD

9:00–9:30 AM **Physiologic outcome measures**
- Edward Sellers, MD, PhD

9:30–10:00 AM **Recommendations for physiologic outcome measures**
- moderated by: Don Jasinski, MD

10:00–10:15 AM **COFFEE BREAK**

10:15–10:45 AM **Performance outcomes measures**
- James Zacny, PhD

10:45–11:15 AM **Recommendations for performance outcome measures**
- moderated by: Richard Foltin, PhD

11:15–11:45 AM **Subjective outcome measures**
- George Bigelow, PhD

11:45–12:30 PM	**Discussions of subjective outcome measures**
	• moderated by: Sharon Walsh, PhD and Ed Sellers, MD, PhD
12:30–1:15 PM	**LUNCH**
1:15–2:00 PM	**Recommendations for subjective outcome measures**
	• moderated by: Sharon Walsh, PhD and Ed Sellers, MD, PhD
2:00–2:30 PM	**Behavioral outcome measures**
	• Sandra Comer, PhD
2:30–3:30 PM	**Recommendations for behavioral outcome measures**
	• moderated by: Bob Balster, PhD, and Chris-Ellyn Johanson, PhD
3:30–4:00 PM	**COFFEE BREAK**
4:00–4:30 PM	**Data analysis**
	• Richard Foltin, PhD
4:30–5:00 PM	**Recommendations for data analysis**
	• moderated by: Richard Foltin, PhD
7:00–9:00 PM	**DINNER**

FRIDAY, OCTOBER 2

7:30–8:00 AM	**CONTINENTAL BREAKFAST**
8:00–8:10 AM	**Meeting objectives and deliverables**
	• Dennis Turk, PhD
8:10–8:30 AM	**A regulatory perspective on what is needed for evaluating abuse liability in analgesic clinical trials**
	• Bob Rappaport, MD
8:30–8:50 AM	**Toward a classification of abuse-related outcomes**
	• Nat Katz, MD
8:50–9:20 AM	**Discussion: background issues and definitions**
	• moderated by…
9:20–9:40 AM	**Clinical assessment of abuse-related outcomes**
	• Charles O'Brien, MD, PhD
9:40–10:00 AM	**Patient-reported and interviewer-rated abuse-related outcomes (e.g., COMM, ABC)**
	• Jennifer Haythornthwaite, PhD

10:00–10:20 AM	**COFFEE BREAK**

10:20–10:40 AM **Urine drug screening in analgesic clinical trials**
- Gary Reisfield, MD

10:40–11:00 AM **Study drug monitoring and diversion in analgesic clinical trials**
- Robert Colucci, PharmD

11:00–12:00 PM **Consensus recommendations for clinical, patient-reported, and behavioral abuse-related outcomes in analgesic**
clinical **trials**
- moderated by…

12:00–1:00 PM **LUNCH**

1:00–1:30 PM **The development of the Columbia Classification Algorithm of Suicide Assessment (C-CASA)**
- Kelly Posner, PhD

1:30–2:10 PM **Retrospective and prospective classification of abuse-related adverse events in analgesic clinical trials**
- Nat Katz, MD

2:10–2:30 PM **Discussant**
- Michael Klein, MD

2:30–2:50 PM **COFFEE BREAK**

2:50–3:10 PM **Consensus recommendations for core abuse-related outcome domains to assess in analgesic clinical trials**
(e.g. **abuse, misuse, diversion, addiction)**
- moderated by…

3:10–4:30 PM **Consensus recommendations for core abuse-related outcome measures and their analysis**
- moderated by…

4:30 **ADJOURN**