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