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

IMMPACT-X

“RESEARCH DESIGN CONSIDERATIONS FOR CLINICAL STUDIES OF ABUSE DETERRENT OPIOID ANALGESICS”

JUNE 2 - 4, 2009
RITZ CARLTON PENTAGON CITY
ARLINGTON, VIRGINIA

TUESDAY, JUNE 2ND

7:00 PM RECEPTION AND DINNER
at the Ritz Carlton

WEDNESDAY, JUNE 3RD

7:00–7:45 AM CONTINENTAL BREAKFAST

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

8:10–8:30 AM Analgesic Clinical Trial Innovations, Opportunities, and Networks (ACTION): an FDA critical path public-private-partnership
• Bob Rappaport, MD

8:30–9:00 AM Scope of the problem of prescription opioid abuse: public health perspective
• Richard Denisco, MD

9:00–9:45 AM Deterrence of prescription opioid abuse: FDA perspective
• Bob Rappaport, MD

9:45–10:15 AM COFFEE BREAK

10:15–10:45 AM Clinical studies of abuse deterrent opioid analgesics: definitions, current approaches, and critical issues
• Nathaniel Katz, MD

10:45–11:45 AM Discussion: critical issues in evaluating abuse deterrent opioid analgesics
• moderated by Dennis Turk

11:45–12:45 PM LUNCH
12:45–1:15 PM  Current status of experimental human abuse liability studies: methods, outcomes, and predictive validity for real-world abuse
   • Sandra Comer, PhD

1:15–1:45 PM  Limitations of experimental human abuse liability studies and prospects for improvement
   • James Zacny, PhD

1:45–2:45 PM  Discussion: research design considerations for human abuse liability studies
   • moderated by Robert Dworkin

2:45–3:15 PM  COFFEE BREAK

3:15–3:45 PM  Retrospective analyses of abuse-related outcomes in clinical trials of analgesic drugs and their interpretation
   • Michael Klein, PhD

3:45–4:00 PM  How can abuse-related outcomes be prospectively evaluated in clinical trials of analgesic drugs?
   • Deborah Leiderman, MD

4:00–5:00 PM  Discussion: research design considerations for evaluating abuse-related outcomes in clinical trials of analgesic drugs
   • moderated by Dennis Turk

7:00–9:00 PM  DINNER

THURSDAY, JUNE 4th

7:00–8:00 AM  CONTINENTAL BREAKFAST

8:00–8:30 AM  Randomized clinical trials of abuse: limitations and prospects for improvement
   • Edgar Adams, ScD

8:30–9:00 AM  Observational and claims data studies of abuse-related outcomes: limitations and prospects for improvement
   • Nabarun Dasgupta, MPH

9:00–10:00 AM  Discussion: research design considerations for studies of abuse-related outcomes
   • moderated by Robert Dworkin

10:00–10:30 AM  COFFEE BREAK
10:30–11:00 AM  The use of poison center data to assess the relative abuse rates of prescription opioids
    • Richard Dart, MD

11:00–11:30 AM  The use of addiction center data to assess abuse of prescription opioids
    • John Brownstein, PhD

11:30–12:30 PM  Discussion: research design considerations for evaluating prescription opioid abuse in poison and addiction center data
    • moderated by Dennis Turk

12:30–1:30 PM     LUNCH

1:30–3:30 PM      Consensus recommendations: design, analysis, and interpretation of clinical studies of abuse deterrent opioid analgesics
    • moderated by Dennis Turk and Robert Dworkin

3:30–3:45 PM     COFFEE BREAK

3:45–4:15 PM     The Resource for Evaluating Procedures and Outcomes of Randomized Trials (REPORT): update
    • moderated by Robert Dworkin

4:15 PM         ADJOURN