

# 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 2<sup>ND</sup>***

**7:00 PM RECEPTION AND DINNER**  
at the Ritz Carlton

***WEDNESDAY, JUNE 3<sup>RD</sup>***

**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**

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|---------------------------------------|--|
| <b>12:45–1:15 PM</b><br>for real-     | <b>Current status of experimental human abuse liability studies: methods, outcomes, and predictive validity world abuse</b> <ul style="list-style-type: none"><li>• Sandra Comer, PhD</li></ul>    |
| <b>1:15–1:45 PM</b>                   | <b>Limitations of experimental human abuse liability studies and prospects for improvement</b> <ul style="list-style-type: none"><li>• James Zacny, PhD</li></ul>                                  |
| <b>1:45–2:45 PM</b>                   | <b>Discussion: research design considerations for human abuse liability studies</b> <ul style="list-style-type: none"><li>• moderated by Robert Dworkin</li></ul>                                  |
| <b>2:45–3:15 PM</b>                   | <b>COFFEE BREAK</b>  |
| <b>3:15–3:45 PM</b><br>interpretation | <b>Retrospective analyses of abuse-related outcomes in clinical trials of analgesic drugs and their</b> <ul style="list-style-type: none"><li>• Michael Klein, PhD</li></ul>                       |
| <b>3:45–4:00 PM</b>                   | <b>How can abuse-related outcomes be prospectively evaluated in clinical trials of analgesic drugs?</b> <ul style="list-style-type: none"><li>• Deborah Leiderman, MD</li></ul>                    |
| <b>4:00–5:00 PM</b><br>drugs          | <b>Discussion: research design considerations for evaluating abuse-related outcomes in clinical trials of analgesic</b> <ul style="list-style-type: none"><li>• moderated by Dennis Turk</li></ul> |
| <b>7:00–9:00 PM</b>                   | <b>DINNER</b>  |

***THURSDAY, JUNE 4<sup>TH</sup>***

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|-----------------------|---|
| <b>7:00–8:00 AM</b>   | <b>CONTINENTAL BREAKFAST</b>  |
| <b>8:00–8:30 AM</b>   | <b>Randomized clinical trials of abuse: limitations and prospects for improvement</b> <ul style="list-style-type: none"><li>• Edgar Adams, ScD</li></ul>                                  |
| <b>8:30–9:00 AM</b>   | <b>Observational and claims data studies of abuse-related outcomes: limitations and prospects for improvement</b> <ul style="list-style-type: none"><li>• Nabarun Dasgupta, MPH</li></ul> |
| <b>9:00–10:00 AM</b>  | <b>Discussion: research design considerations for studies of abuse-related outcomes</b> <ul style="list-style-type: none"><li>• moderated by Robert Dworkin</li></ul>                     |
| <b>10:00–10:30 AM</b> | <b>COFFEE BREAK</b>   |

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|-----------------------|--|
| <b>10:30–11:00 AM</b> | <b>The use of poison center data to assess the relative abuse rates of prescription opioids</b> <ul style="list-style-type: none"><li>• Richard Dart, MD</li></ul>   |
| <b>11:00–11:30 AM</b> | <b>The use of addiction center data to assess abuse of prescription opioids</b> <ul style="list-style-type: none"><li>• John Brownstein, PhD</li></ul>   |
| <b>11:30–12:30 PM</b> | <b>Discussion: research design considerations for evaluating prescription opioid abuse in poison and addiction center data</b> <ul style="list-style-type: none"><li>• moderated by Dennis Turk</li></ul>              |
| <b>12:30–1:30 PM</b>  | <b>LUNCH</b>   |
| <b>1:30–3:30 PM</b>   | <b>Consensus recommendations: design, analysis, and interpretation of clinical studies of abuse deterrent analgesics</b> <ul style="list-style-type: none"><li>• moderated by Dennis Turk and Robert Dworkin</li></ul> |
| <b>opioid</b>         |  |
| <b>3:30–3:45 PM</b>   | <b>COFFEE BREAK</b>  |
| <b>3:45–4:15 PM</b>   | <b>The Resource for Evaluating Procedures and Outcomes of Randomized Trials (REPORT): update</b> <ul style="list-style-type: none"><li>• moderated by Robert Dworkin</li></ul>   |
| <b>4:15 PM</b>        | <b>ADJOURN</b>   |