



**ABUSE LIABILITY EVALUATION FOR RESEARCH, TREATMENT, AND TRAINING
(ALERTT) WORKING GROUP**

**RECOMMENDATIONS FOR IDENTIFYING, CLASSIFYING, AND DEFINING ABUSE-RELATED EVENTS
IN CLINICAL TRIALS**

**NOVEMBER 28 - 29, 2012
PALOMAR HOTEL
WASHINGTON, DC**

TUESDAY, NOVEMBER 27

7:00 PM Welcome Reception & Dinner

WEDNESDAY, NOVEMBER 28

7:30 - 8:30 AM Continental Breakfast

8:30 - 8:45 AM Welcome and Introductions
• *Dennis Turk, PhD, and Bob Dworkin, PhD*

**8:45 - 9:15 AM The Need to Classify and Define Abuse-related Events in
Clinical Trials**
• *Bob Rappaport, MD*

9:15 - 9:30 AM Q & A

9:30 - 10:00 AM The Classification and Assessment of Suicidality at the FDA
• *Mitchell Mathis, MD*

10:00 - 10:15 AM Q & A

10:15 - 10:30 AM Break

10:30 - 11:00 AM Classifying Abuse-related Events: the RADARS Experience
• *Richard Dart, MD, PhD*

11:00 - 11:15 AM Q & A

**11:15 - 11:45 AM A Proposed Classification of Abuse-related Events for
Clinical Trials**
• *Celia Winchell, MD*

**11:45 AM - 12:30 PM Proposed Definitions for Abuse-related Events for
Clinical Trials *with Example Cases***
• *Silvia Calderon, PhD*



- 12:30 - 1:30 PM** **Lunch**
- 1:30 - 3:00 PM** **Q & A and Panel Discussion on Classification and Definitions**
- *Moderators: Bob Dworkin, PhD and Dennis Turk, PhD*
 - *Katherine Bonson, PhD, Silvia Calderon, PhD, Sharon Hertz, MD, Bob Rappaport, MD, Celia Winchell, MD*
- 3:00 - 3:15 PM** **Break**
- 3:15 - 4:30 PM** **Q & A and Panel Discussion on Classification and Definitions (continued)**
- *Moderators: Bob Dworkin, PhD and Dennis Turk, PhD*
 - *Katherine Bonson, PhD, Silvia Calderon, PhD, Sharon Hertz, MD, Bob Rappaport, MD, Celia Winchell, MD*
- 7:00 - 9:00 PM** **Dinner**
- THURSDAY, NOVEMBER 29**
- 7:30 - 8:30 AM** **Continental Breakfast**
- 8:30 - 9:00 AM** **Drug Accounting Discrepancies and Other Triggering Events for Abuse-related Events in Clinical Trials, with Example Cases**
- *Nathaniel Katz, MD*
- 9:00 - 9:30 AM** **Q & A and Panel Discussion on Triggering Events**
- *Moderators: Bob Dworkin, PhD and Dennis Turk, PhD*
 - *Silvia Calderon, PhD, Sharon Hertz, MD, Nathaniel Katz, MD, Bob Rappaport, MD, Celia Winchell, MD*
- 9:30 - 10:00 AM** **Proposed Procedures for Adjudicating Classification of Abuse-related Events in Clinical Trials**
- *Nathaniel Katz, MD*
- 10:00 - 10:30 AM** **Q & A and Panel Discussion on Adjudication Procedures**
- *Moderators: Bob Dworkin, PhD and Dennis Turk, PhD*
 - *Silvia Calderon, PhD, Sharon Hertz, MD, Nathaniel Katz, MD, Bob Rappaport, MD, Celia Winchell, MD*
- 10:30 - 11:00 AM** **Break**



11:00 AM - 12:30 PM

Group Discussion: Consensus Recommendations for Identifying, Classifying, and Defining Abuse-related Events In Clinical Trials

- *Moderators: Bob Dworkin, PhD, Bob Rappaport, MD, Dennis Turk, PhD*

12:30 - 1:30 PM

Lunch

1:30 - 4:00 PM

Group Discussion:

- (1) Consensus Research Agenda for Identifying, Classifying, and Defining Abuse-related Events in Clinical Trials**
- (2) Next Steps for the Prospective Assessment of Abuse Liability in Clinical Trials**

- *Moderators: Bob Dworkin, PhD, Sharon Hertz, MD, Bob Rappaport, MD, Dennis Turk, PhD*