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

ALERTT - II

RECOMMENDATIONS FOR QUANTIFYING ABUSE-RELATED EVENTS IN CLINICAL TRIALS

JUNE 27-28, 2013
WESTIN GEORGETOWN HOTEL
WASHINGTON, DC

WEDNESDAY, JUNE 26

7:00 PM	**RECEPTION AND DINNER (at the Westin)**

THURSDAY, JUNE 27

7:30 – 8:00 AM	**CONTINENTAL BREAKFAST**
8:00 – 8:15 AM	**Overview and Introductions** • *Dennis C. Turk, PhD and Robert H. Dworkin, PhD*
8:15 – 8:30 AM	**Regulatory Perspective** • *Douglas Throckmorton, MD*
8:30 – 8:45 AM	**The Importance of Quantifying Abuse-related Events in Clinical Trials** • *Bob Rappaport, MD*
8:45 – 9:15 AM	**Measuring Abuse-Related Events in Clinical Trials: industry Perspective** • *Stephen Wright, MD*
9:15 – 9:45 AM	**Review of Categories and Definitions of Abuse-related Events** • *Shannon Smith, PhD*
9:45 – 10:15 AM	**Q & A and Panel Discussion** • *Michael Klein, PhD, Ernest A. Kopecky, PhD, MBA, Bob Rappaport, MD, Shannon Smith, PhD, Stephen Wright, MD*
10:15 – 10:45 AM	**BREAK**
10:45 – 11:15 AM	**A System for the Retrospective Analysis of Abuse-related Events in Clinical Trials: Background and Overview** • *Nathaniel Katz, MD*

11:15 – 11:45 AM **Selection of "Triggering Adverse Events": Background and Preliminary Data**
- *Judith K. Jones, MD, PhD*

11:45 AM – 12:15 PM **Retrospective System for Evaluating Abuse-related Events: Usability Study and Validation Plans**
- *Jeremiah Trudeau, PhD*

12:15 – 1:15 PM **LUNCH**

1:15 – 1:45 PM **Q & A**
- *Judith K. Jones, MD, PhD, Nathaniel Katz, MD, Jeremiah Trudeau, PhD*

1:45 – 2:45 PM **Group Discussion: Preliminary Recommendations for the Retrospective Evaluation of Abuse-related Events in Clinical Trials**
- *Moderators: Robert H. Dworkin, PhD and Dennis C. Turk, PhD*

2:45 – 3:15 PM **BREAK**

3:15 – 3:45 PM **Measures of Abuse in Clinical Trials: A Systematic Review**
- *Shannon Smith, PhD*

3:45 – 4:15 PM **Development of an Instrument to Measure Misuse, abuse, and diversion**
- *Carl L. Roland, PharmD, MS and Beatrice Setnik, PhD*

4:15 – 4:45 PM **Developing Novel Systems for the Prospective Analysis of Abuse-related Events in Clinical Trials: Scientific Issues**
- *Nathaniel Katz, MD*

4:45 – 5:15 PM **Q & A**
- *Nathaniel Katz, MD, Carl L. Roland, PharmD, MS, Beatrice Setnik, PhD, Shannon Smith, PhD*

7:00 – 9:00 PM **DINNER**

FRIDAY, JUNE 28

7:30 – 8:00 AM **CONTINENTAL BREAKFAST**

8:00 – 8:30 AM **A Novel System for the Prospective Analysis of Abuse-related Events in Clinical Trials: Overview**
- *Nathaniel Katz, MD*

8:30 – 9:30 AM	**Development and Evaluation of System Elements: Questionnaires, Triggering Criteria, Usability, and Reliability** • *Jeremiah Trudeau, PhD*
9:30 – 10:00 AM	**Q & A** • *Nathaniel Katz, MD, Jeremiah Trudeau, PhD*
10:00 – 10:30 AM	**BREAK**
10:30 AM – 12:00 PM	**Panel Discussion: Prospective Evaluation of Abuse-related Events in Clinical Trials** • *Richard Dart, MD, PhD, J. David Haddox, DDS, MD, Sharon Hertz, MD, Nathaniel Katz, MD, Jeremiah Trudeau, PhD, Gary J. Vorsanger, PhD, MD*
12:00 – 1:00 PM	**LUNCH**
1:00 – 2:30 PM	**Group Discussion: Preliminary Recommendations for the Prospective Evaluation of Abuse-related Events in Clinical Trials** • *Moderators: Dennis C. Turk, PhD and Robert H. Dworkin, PhD*
2:30 – 3:00 PM	**BREAK**
3:00 – 4:00 PM	**Consensus Recommendations: Retrospective and Prospective Evaluation of Abuse-related Events in Clinical Trials** • *Moderators: Robert H. Dworkin, PhD and Dennis C. Turk, PhD*