Clinically Meaningful Substance Abuse Treatment Outcome Measure for Effectiveness Trials

Bethesda North Marriott Hotel & Conference Center
Bethesda, Maryland
December 15 – 16, 2009

Rationale and Objectives

The Society for Research on Nicotine and Tobacco (SRNT) has recommended that prolonged abstinence be used as the primary outcome measure in smoking cessation clinical trials. For alcohol use, the research field has defined five or more drinks for men and four or more drinks for women as meaningful thresholds in clinical trials.

The drug abuse field has not quantitatively defined serious drug use or abstinence. It has not provided solid milestones, thresholds, or measures for illicit drug use. Therefore, clinical outcomes are inconsistent across trials, making it difficult to compare the efficacy/effectiveness of treatments from different trials.

The main objective of this workshop is for leaders in the drug abuse field (researchers and practicing clinicians) to address the following two questions:

1. **What to measure?** What is the most appropriate primary outcome measure on drug use for clinical trials in drug abuse treatment research?
2. **How to measure it?** What is the most appropriate approach (e.g., instrument, algorithm, or procedure) for capturing this outcome measure?

The expected outcome of the meeting is a general consensus on:

1. **The current state of the science.** What do research and current clinical practice tell us regarding the two questions above?
2. **The next research steps needed.** What additional research is needed to address important gaps that will help us answer the above two questions?

Discussions on how to define a clinically meaningful *difference* between treatments (treatment effect) or on how to handle missing data are *not* part of the objectives of this workshop.

Organizers, with assistance from panel leaders and members, plan to compile recommendations and issue a report approximately 4 months after the workshop. They will also coordinate the publication of a scientific paper with expert recommendations regarding the two workshop objective questions within 1 year after the meeting.

Agenda Day One
Tuesday, December 15, 2009

8:30 – 8:45 a.m. **Welcome**
Nora D. Volkow, M.D.
Director
National Institute on Drug Abuse

8:45 – 9:00 a.m. **Opening Remarks**
Meeting Objectives, Goals and Expectations, Rules of Engagement

Science Meeting Planning Committee
Carmen Rosa, M.S.
National Institute on Drug Abuse

Paul Wakim, Ph.D.
National Institute on Drug Abuse

Jack Blaine, M.D.
National Institute on Drug Abuse

9:00 – 10:15 a.m. **Introductory Session**
Alcohol Experience
G. Alan Marlatt, Ph.D.
University of Washington

Tobacco Experience
John Hughes, M.D.
University of Vermont

Mental Health (Depression) Experience
Madhukar Trivedi, M.D.
University of Texas Southwestern Medical Center

10:15 – 10:30 a.m. ***Break***

10:30 –11:00 a.m. **History of Outcome Measures in Substance Abuse Effectiveness Trials**
Dennis Donovan, Ph.D.
University of Washington

John Hamilton
Regional Network of Programs, Inc.

11:00 – 12:45 p.m.	**Panel I—State of the Science in Assessing Drug Use in Clinical Research: Biological Measures** *Eugene Somoza, M.D., Ph.D.* *University of Cincinnati* *Marilyn Huestis, Ph.D.* *National Institute on Drug Abuse* *Walter Ling, M.D.* *University of California, Los Angeles*
12:45 – 2:15 p.m.	***Lunch***
2:15 – 2:30 p.m.	**Panel I Summary** *Dennis Daley, Ph.D., L.S.W.* *University of Pittsburgh Medical Center*
2:30 – 4:30 p.m.	**Panel II—State of the Science in Assessing Drug Use in Clinical Research: Self-Reported Measures** *Kenzie Preston, Ph.D.* *National Institute on Drug Abuse* *Kathleen Carroll, Ph.D.* *Yale School of Medicine* *Patrick Flynn, Ph.D.* *Texas Christian University* *Allan Cohen, M.A., M.F.T.* *Bay Area Addiction Research and Treatment, Inc.*
4:30 – 4:45 p.m.	**Panel II Summary** *Robert Lindblad, M.D.* *The EMMES Corporation*
4:45 – 5:00 p.m.	**Day 1 Summary** *Science Meeting Planning Committee*
5:00 p.m.	***Adjournment***

Agenda Day Two
Wednesday, December 16, 2009

8:00 – 8:15 a.m. **Opening Remarks**
Science Meeting Planning Committee

8:15 – 10:45 a.m. **Panel III—Primary Outcome Measure**
George Bigelow, Ph.D.
Johns Hopkins University School of Medicine

Roger Weiss, M.D.
Harvard Medical School

Elizabeth Wells, Ph.D.
University of Washington

John Gardin, Ph.D.
ADAPT, Inc.

Daniel Feaster, Ph.D.
University of Miami Miller School of Medicine

David Epstein, Ph.D.
National Institute on Drug Abuse

Celia Winchell, M.D.
U.S. Food and Drug Administration

10:45 – 11:00 a.m. **Panel III Summary**
Gregory Brigham, Ph.D.
*Maryhaven, Inc***.**

11:00 – 11:15 a.m. ***Break***

11:15 – 12:15 p.m. **Panel IV—Other Important Measures to Consider**
Shelly Greenfield, M.D., M.P.H.
Harvard Medical School

Ron Jackson, M.S.W.
Evergreen Treatment Services

Deni Carise, Ph.D.
Treatment Research Institute

Stephen Tiffany, Ph.D.
University of Buffalo, The State University of New York

Deborah Hasin, Ph.D.
Columbia University

12:15 – 1:30 p.m. ***Lunch***

1:30 – 3:00 p.m. **Panel IV Continued**

3:00 – 3:15 p.m. **Panel IV Summary**
Lawrence Friedman, M.D.
Center for Clinical Trials Network Consultant

3:15 – 3:30 p.m. ***Break***

3:30 – 4:30 pm. **Recommendations and Next Steps**
Dennis Daley, Ph.D., L.S.W.
University of Pittsburgh Medical Center

Eugene Somoza, M.D., Ph.D.
University of Cincinnati

Robert Lindblad, M.D.
The EMMES Corporation

Kenzie Preston, Ph.D.
National Institute on Drug Abuse

Gregory Brigham, Ph.D.
Maryhaven, Inc.

George Bigelow, Ph.D.
Johns Hopkins University School of Medicine

Lawrence Friedman, M.D.
Center for Clinical Trials Network Consultant

Shelly Greenfield, M.D., M.P.H.
Harvard Medical School

4:30 p.m. ***Meeting Adjourned***