ACT-AD
Accelerate Cure/Treatments for Alzheimer's Disease

TRANSFORMING SCIENCE SWHR SOCIETY FOR WOMEN'S HEALTH RESEARCH

Clinical Meaningfulness in Drug Development for Early Alzheimer's Disease
An FDA/Alzheimer's Disease Allies Meeting

Marriott Hotel & Conference Center
5701 Marinelli Road
Bethesda, MD 20852

November 6, 2014

OBJECTIVES

In 2008 and 2009, ACT-AD sponsored two meetings examining how to determine clinical meaningfulness in later stages of Alzheimer's disease. In 2013 the FDA published a draft guidance for industry on therapeutic development for early Alzheimer's disease. This draft guidance provides an overview of the Agency's thinking on requirements for demonstrating clinical meaningfulness in clinical trials of earlier stage Alzheimer's patients.

This meeting will explore challenges related to the current means of measuring clinical meaningfulness at earlier stages of Alzheimer's disease, including mild Alzheimer's dementia; how to balance the needs of all stakeholders in the drug development process who seek more effective treatments; and begin to forge agreement on current strategies for demonstrating clinical meaningfulness in existing trials of early patients and how they might inform approaches for future trials.

WELCOME

7:30– 8:00 a.m.	**Registration and Breakfast**
8:00-8:30 a.m.	**Welcome** Dan Perry, ACT-AD Phyllis Greenberger, Society for Women's Health Research

PRESENTATIONS

8:30-8:45 a.m.	**Update on Building the Integrative Alzheimer's Trial Database** Kun Jin, PhD, U.S. Food and Drug Administration
8:40-8:45 a.m.	**Q&A**
8:50-9:20 a.m.	**Challenges with Defining Clinical Meaningfulness in CNS Diseases** Richard Keefe, PhD, Duke University

9:20-9:50 a.m. **Q&A**

9:50-10:20 a.m. **Research on Declines in Cognition and Function in Early AD**
Paul Aisen, MD, UCSD

10:20-10:50 a.m. **Q&A**

10:50-11:30 a.m. **Break**

PANEL

11:30-12:30 p.m. **Demonstrating clinical meaningfulness in current trials and fostering efforts to develop tools for use in future trials**

Panelists: Paul Aisen, MD, UCSD (Moderator)
Eric Bastings, MD, U.S. Food and Drug Administration
Billy Dunn, MD, U.S. Food and Drug Administration
Suzanne Hendrix, PhD, Pentara
Janice Hitchcock, PhD, Eli Lilly
Nicholas Kozauer, MD, Quintiles
Ranjit Mani, MD, U.S. Food and Drug Administration

12:30– 1:30 p.m. **Q&A**

CLOSING

1:30-2:00 p.m. **Concluding Remarks**
Dan Perry, ACT-AD

** Snacks will be available during the 10:50 break and boxed lunches will be available at 12:30*