



**Measures of Clinical Meaningfulness:  
An AD Ally/FDA Scientific Workshop**

***March 13, 2008  
Hilton Rockville, Rockville, MD***

**AGENDA**

**7:30 - 8:00 Continental breakfast**

**8:00 - 8:15 Joint Welcome**

- Eric Hall, Member, ACT-AD Advisory Committee, President and CEO, Alzheimer's Foundation of America
- Bill Thies, PhD, Vice President, Medical and Scientific Relations, Alzheimer's Association
- Robert Egge, Executive Director, Alzheimer's Study Group

**Moderator:** Dan Perry, Chairman, ACT-AD

**8:15 - 9:00 Current FDA Standards for Defining Clinical Meaningfulness in Alzheimer's Disease Treatments**

- Russell Katz, MD, Director, Division of Neurology Products, FDA

**9:00 - 9:30 Issues and Challenges in the Context of the Current Standards for Defining Clinical Meaningfulness in Alzheimer's Disease**

- David Knopman, MD, Department of Neurology, Mayo Clinic

**9:30 - 10:00 Options and Alternatives for Defining Clinical Meaningfulness in Alzheimer's From Early Diagnosis through the Disease Spectrum**

- Jeffrey Cummings, MD, Director, Alzheimer's Disease Center, University of California, Los Angeles

**10:00 - 10:30 Meaningful Changes as Viewed by the Clinician, Patient and Caregiver**

- Howard Fillit, MD, Executive Director, Alzheimer's Drug Discovery Foundation

**10:30 - 10:45 Break**

**10:45 - 12:15 Challenges Facing Stakeholders, Regulators and Industry** (Panel discussion)

**Moderator:** Sid Gilman, MD, FRCP, William J. Herdman Distinguished University Professor of Neurology, University of Michigan

- **Patient and Caregivers:** Bill Bridgewater, FDA Patient Consultant, Twyla Bridgewater, FDA Caregiver Consultant and Meryl Comer, Caregiver and President, Geoffrey Beene Foundation Alzheimer's Initiative
- **Physician/ Neurologist:** David Knopman, MD, Department of Neurology, Mayo Clinic and Jeffrey Cummings, MD, Director, Alzheimer's Disease Center, University of California, Los Angeles
- **Gerontologist Advocate:** Howard Fillit, MD, Executive Director, Alzheimer's Drug Discovery Foundation
- **FDA:** Russell Katz, MD, Director, Division of Neurology Products, FDA and Robert Temple, MD, Director of Office of Drug Evaluation, FDA
- **Industry:** Dale Schenk, PhD, Executive Vice President and Chief Scientific Officer, Elan

**12:15 - 12:30 Discussion and Q&A**

**12:30 - 12:45 Summary and Next Steps**

- Sid Gilman, MD, FRCP, William J. Herdman Distinguished University Professor of Neurology, University of Michigan

Box lunches provided