

# ACT-AD

Accelerate Cure/Treatments for Alzheimer's Disease

## 9<sup>th</sup> Annual FDA/Alzheimer's Disease Allies Meeting

*Starting with the End in Mind:  
Aligning the Science to Close Gaps in Alzheimer's Disease Therapeutic  
Development*

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

**November 16, 2016**

### OBJECTIVES

In September of 2015, the Accelerate Cure/Alzheimer's Disease (ACT-AD) Coalition held its 8<sup>th</sup> annual meeting in response to the U.S. Food and Drug Administration's (FDA) [report](#) on progress toward targeted drug therapy for Alzheimer's disease (AD). This meeting began a discussion about the state of research into the underlying causes of Alzheimer's disease and pathways for successful treatment. Participants left encouraged by significant research investments in the public and private sectors they anticipated were on track to fill the knowledge gaps FDA identified.

ACT-AD's November 16, 2016 meeting will build on the 2015 gathering and explore whether federal research and regulatory review align to definitively close knowledge gaps in clinical development. The meeting will review the most recent research on Alzheimer's disease pathology and genetics; efforts to identify reliable biomarkers in disease-modifying treatment trials; and novel symptomatic approaches to improve major behavioral and psychiatric aspects of the disease. The program will conclude with an open exchange about how findings from current studies can be practically applied to improve the prospects for successful Alzheimer's disease treatment in the future.

### WELCOME

- 9:30– 10:00 a.m.      **Registration and Breakfast**
- 10:00-10:15 a.m.      **Welcome and Introduction**  
Cynthia Bens, ACT-AD

### PRESENTATIONS

- 10:15-10:45 a.m.      **NIH Initiatives to Inform Alzheimer's Disease Therapeutic  
Development**  
Richard Hodes, M.D., National Institute on Aging

- 10:45-11:00 a.m. **Q&A**
- 11:00-11:30 a.m. **Genetic and Biomarker Advances from Clinical Trials in Early Alzheimer's Disease**  
Carole Ho, M.D., Denali  
Vissia Viglietta, M.D., PhD, Biogen
- 11:30-11:45 a.m. **Q&A**
- 11:45-12:00 p.m. **Break**
- 12:00-12:15 p.m. **Findings from Current Trials Treating Behavioral and Psychiatric Symptoms of Alzheimer's Disease**  
Paul Rosenberg, M.D., Johns Hopkins
- 12:15-12:30 p.m. **Q&A**
- 12:30-1:30 p.m. **Lunch**

#### **PANEL**

- 1:30-2:30 p.m. **Scientific and regulatory considerations for developing meaningful disease modifying and symptomatic Alzheimer's disease treatments**
- Panelists: Billy Dunn, M.D., U.S. Food and Drug Administration  
Mitchell Mathis, M.D., U.S. Food and Drug Administration (Invited)  
Yaakov Stern, Ph.D., Columbia University  
Sanjay Dubé, M.D., Avanir  
Michael Irizarry, M.D., Eli Lilly and Company  
Richard Meibach, Ph.D., Novartis

- 2:30– 3:30 p.m. **Q&A**

#### **CLOSING**

- 3:30-4:00 p.m. **Summary and Concluding Remarks**  
Cynthia Bens, ACT-AD