



**Regulatory Science Panel**  
*Dan Perry, President and CEO*  
*Alliance for Aging Research*  
May 4, 2010



[convention.bio.org](http://convention.bio.org)

May 3-6, 2010 • Monday–Thursday • Chicago, IL USA



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

**ACT-AD is a diverse coalition of 50+ national organizations that seeks to:**

- Generate immediate public and government recognition of Alzheimer's as a debilitating, dehumanizing and life-threatening disease that requires urgent attention
- Bring transformational therapies to patients, providers and families in the next decade by making the acceleration of promising Alzheimer's therapies a top national priority

## ACT-AD Coalition Members

### Advisory Council

- Alliance for Aging Research
- Alzheimer's Foundation of America
- American Society on Aging
- National Alliance for Caregiving
- National Association of Area Agencies on Aging
- National Consumers League
- Research!America
- Society for Women's Health Research
- Abigail Alliance
- Academy of Correctional Health Professionals
- American Academy of Ambulatory Care Nursing
- American Association for Geriatric Psychiatry
- American Association of Colleges of Nursing
- American Federation for Aging Research
- American Medical Students Association (AMSA)
- American Medical Women's Association
- American Nurses Association
- American Psychological Association
- American Public Health Association
- American Society of Consultant Pharmacists
- Association of Jewish Aging Services
- B'nai B'rith International

## ACT-AD Coalition Members (Cont.)

- Business and Professional Women/USA
- Center for the Advancement of Health
- Faster Cures
- Gerontological Society of America
- Hadassah
- Institute for the Study of Aging
- International Eye Foundation
- International Longevity Center - USA
- Men's Health Network
- National Academy of Elder Law Attorneys
- National Asian Pacific Center on Aging
- National Association for Home Care
- National Association of Senior Companion Project Directors
- National Business Group on Health
- National Commission on Correctional Health Care
- National Council on Patient Information and Education
- National Electrical Manufacturers Association
- National Indian Council On Aging
- National Mental Health Association
- National Palliative Care Research and Training Center
- National Partnership for Women & Families
- National Senior Citizens Law Center
- National Women's Health Network
- Older Women's League
- RetireSafe
- Strategic Health Policy International

## Obstacles to Therapeutic Development for Alzheimer's Disease

- Many trials to date focused on patients too far along in the disease course
- Need to study effects of treatments in very early and pre-symptomatic stages of the disease
- Difficulty in demonstrating clinical meaningful benefit to patients who are not yet symptomatic
- Lack of consensus around the use of biomarkers as surrogate endpoints in trials for early stage and prevention
- Size and length of Phase II studies is growing; need to examine how to maximize the efficiency of trials

## Major ACT-AD Activities

- |                |  |
|----------------|--|
| July 2006      | <ul style="list-style-type: none"><li>• Urge FDA increase priority and urgency for AD</li></ul>  |
| August 2006    | <ul style="list-style-type: none"><li>• Recommend coordinated FDA office for AD</li></ul>  |
| July 2007      | <ul style="list-style-type: none"><li>• Propose series of “Alzheimer’s Allies” meeting with clinical experts</li></ul>   |
| July 2007      | <ul style="list-style-type: none"><li>• FDA announces Neurology Working Group across divisions</li><li>• FDA extends Patient Consultation Program to AD</li></ul>                  |
| March 2008     | <ul style="list-style-type: none"><li>• ACT-AD, Alzheimer’s Assn., Alzheimer’s Study group co-host first Alzheimer’s Allies meeting with FDA neurology in-line reviewers</li></ul> |
| September 2008 | <ul style="list-style-type: none"><li>• Organizes AD clinician leadership petition on AD Biomarkers</li></ul>  |
| July , 2009    | <ul style="list-style-type: none"><li>• Second AD Allies meeting on clinical meaningfulness in early AD</li></ul>  |
| January 2010   | <ul style="list-style-type: none"><li>• Agreement to plan third clinical expert meeting on improving Phase II trial design in Alzheimer’s</li></ul>                                |



## Other Challenges in Aging

- Roughly 45% of the U.S. elder population has Sarcopenia
- Consequences of Sarcopenia
  - weakness
  - reduced mobility
  - functional disability
  - increased mortality
  - negative effects on co-morbid conditions (e.g. glycemic control in diabetes)
  - vulnerability to falls, hospitalization, and institutionalization
- U.S. healthcare costs related to Sarcopenia were \$18.5 billion in 2000

## Regulatory Science Agenda for Sarcopenia

- Lacking clinical definition
- No consensus on measures or outcomes
- No clear pathway for registering therapies
- Limited interest from industry





# Thank you

For more information

[www.agingresearch.org](http://www.agingresearch.org)

[www.act-ad.org](http://www.act-ad.org)