

Advancing Science.
Enhancing Lives.



Navigating CDER: What You Should Know for Effective Engagement

FDA Public Workshop
FDA White Oak Campus
March 31, 2016

Cynthia A. Bens, Vice President of Public Policy

About the Alliance



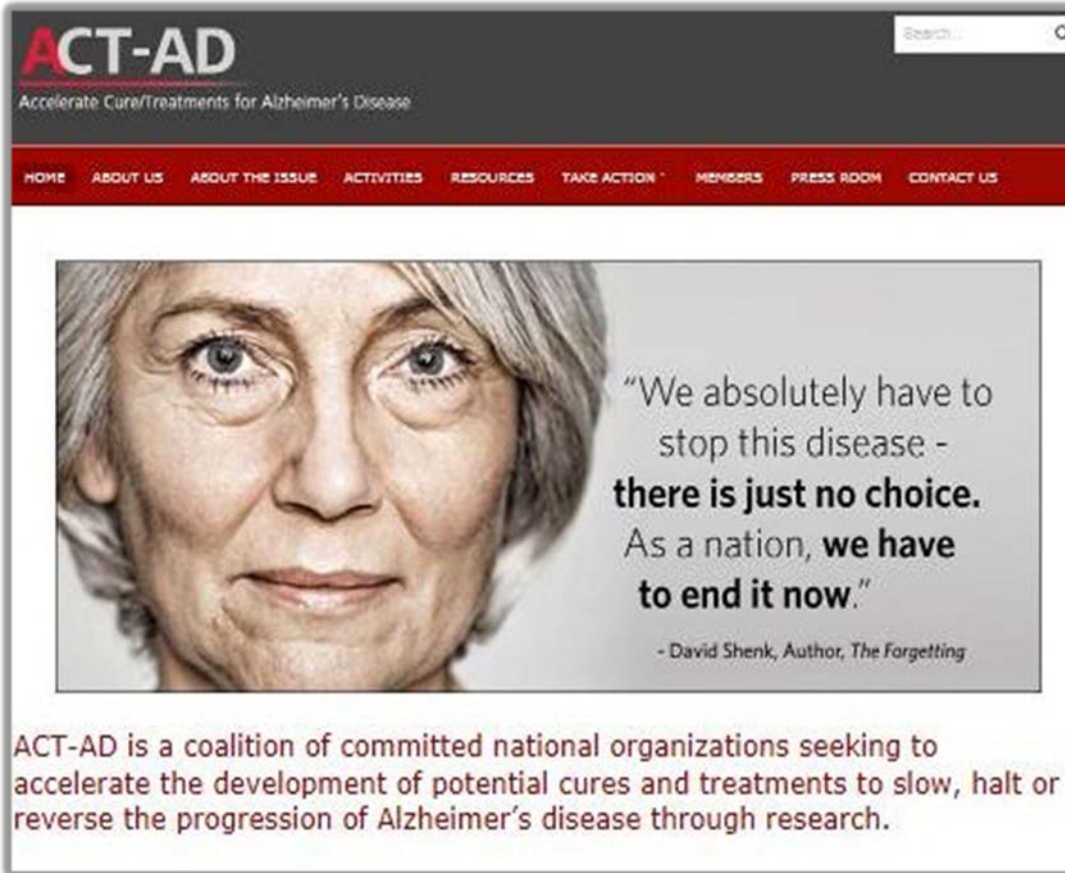
WHO WE ARE

The Alliance for Aging Research is the leading non-profit organization dedicated to accelerating the pace of scientific discoveries and their application in order to vastly improve the universal human experience of aging and health.

www.agingresearch.org

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ACT-AD Coalition



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

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"We absolutely have to stop this disease - there is just no choice. As a nation, we have to end it now."
- David Shenk, Author, *The Forgetting*

ACT-AD is a coalition of committed national organizations seeking to accelerate the development of potential cures and treatments to slow, halt or reverse the progression of Alzheimer's disease through research.

53 Non-profit Members

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**AGING
IN
MOTION**

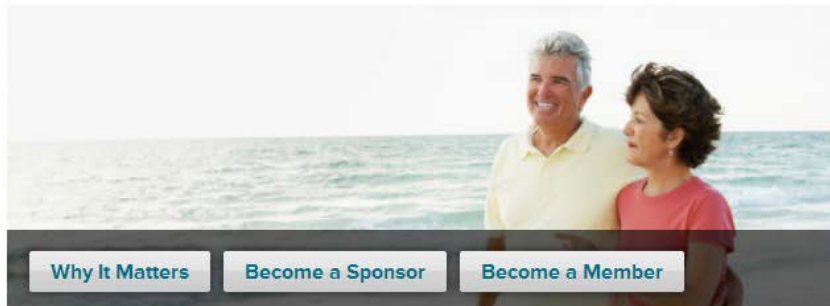
Advancing research and treatment
of sarcopenia and age-related
functional decline

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WELCOME TO AGING IN MOTION

Aging in Motion (AIM) is a coalition of organizations working to advance research and treatment of sarcopenia and age-related functional decline.



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Key Lessons

- Educate yourself on the clinical trial process
- Learn what information is useful for regulatory purposes
- Reconcile your goals with those of the research community and regulated industry
- Work with other advocacy groups in your space
- Listen when FDA speaks about your disease
- Successful engagement does not always=drug approvals
- Acknowledge when FDA has gone above and beyond

CDER Hall of Fame for Engagement



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Thank you for your attention.
Questions? Comments?

Cynthia Bens, Vice President of Public Policy

Email: cbens@agingresearch.org

Phone: 202-688-1230