Navigating CDER: What You Should Know for Effective Engagement

FDA Public Workshop
FDA White Oak Campus
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Cynthia A. Bens, Vice President of Public Policy
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

ACT-AD Coalition

53 Non-profit Members

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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.
AIM Coalition

35 Non-profit Members

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Industry Partners
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Cytokinetics
Hologic
Nutricia Advanced Medical Nutrition

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

**Office of the Center Director**
Janet Woodcock, M.D.
Theresa Mullin, Ph.D.
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**Office of Drug Evaluation-1**
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**Professional Affairs and Stakeholder Engagement**
John Whyte, M.D.
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**Office of Health and Constituent Affairs**
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Thank you for your attention.
Questions? Comments?

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