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

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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?

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