

Randomized Controlled Trials for Alzheimer's Disease

**Advisory Council for Research, Care and
Services**

**US National Plan
to Address Alzheimer's Disease**



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National Alzheimer's Project Act

Goal

**To effectively treat Alzheimer's
disease (delay onset, slow
progression) by**

2025



RCT's for Alzheimer's Disease

Challenges

12 Phase 3 failures in the past 10 years

Last drug approved by the FDA for AD: 2003

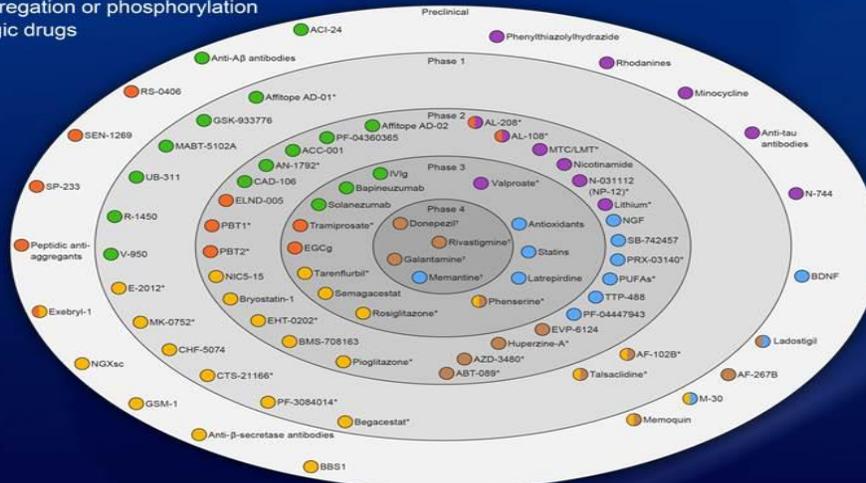
332 active trials for Alzheimer's disease on clinicaltrials.gov



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Drug Development in Alzheimer's Disease

- ↓ Aβ production
- ↓ Aβ aggregation
- ↑ Aβ clearance (immunotherapy)
- ↓ tau aggregation or phosphorylation
- Cholinergic drugs
- Others



Mangialasche et al: Lancet Neurol; 9:702, 2010

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RCT Recruitment

- Trials large, long, expensive, inefficient
- FDA trying to help the process
- Often the major impediment to the execution of a RCT in AD is participant recruitment



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US Plan to Address Alzheimer's Disease

- **Action 1.B.3: Increase enrollment in clinical trials and other clinical research**
- through community, national, and international outreach
Increased enrollment in clinical trials is crucial for the development of better treatments and ultimately a cure for AD. Participating in clinical trials and other research enables volunteers to access the latest experimental approaches available and provides them with care by clinical research staff.



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NIH Alzheimer' Disease Research Summits

- Recommendations include language like:
 - *Expand large-scale registries and natural history cohorts of healthy individuals from early midlife to late-life as well as individuals with subjective and/or objective cognitive impairment and use the data to inform clinical trial design. These cohorts should be population-based and should oversample underrepresented ethnic minorities and groups with lower education.*



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Clinical Trials in ADRD: Recruitment Challenges

- Overview
- FDA Perspective
- NIA Perspective
- PCORI
- BAI's Alzheimer's Prevention Registry
- Global Alzheimer's Platform
- Alzheimer's Association TrialMatch



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February 3, 2017 -- Advisory Council Meeting #23

The meeting was held on Friday, February 3, 2017, in Washington, DC. The theme of this Advisory Council meeting was clinical trials for Alzheimer's disease and related dementias and recruitment challenges. Additional afternoon presentations included updates on progress towards a Care and Services Summit, federal workgroup updates, and preparation for the Advisory Council's 2017 Recommendations, due in April 2017. Material available from this meeting is listed below and is also available at <https://aspe.hhs.gov/advisory-council-alzheimers-research-care-and-services-meetings#Feb2017>.

Comments and questions, or alerts to broken links, should be sent to napa@hhs.gov.

General Information

Agenda	[HTML Version] [PDF Version]
Meeting Announcement	[HTML Version] [PDF Version]
Meeting Summary	[HTML Version] [PDF Version]
Public Comments	[HTML Version]

Handouts

Panelist Bios	[HTML Version] [PDF Version]
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Presentation Slides

2017 Recommendations	[HTML Version] [PDF Version]
Alzheimer's Association TrialMatch	[HTML Version] [PDF Version]
Clinical Services Subcommittee Federal Update	[HTML Version] [PDF Version]
Clinical Studies Recruitment Strategy	[HTML Version] [PDF Version]
Development and Use of Registries to Accelerate Enrollment into Alzheimer's Trials	[HTML Version] [PDF Version]
Long-Term Services and Supports Committee Update	[HTML Version] [PDF Version]
National Recruitment Strategy	[HTML Version] [PDF Version]

NINDS Update	[HTML Version] [PDF Version]
Randomized Controlled Trials for Alzheimer's Disease	[HTML Version] [PDF Version]
Strategies to Facilitate Recruitment and Screening for Alzheimer's Clinical Trials	[HTML Version] [PDF Version]
Transforming AD Therapy Development	[HTML Version] [PDF Version]
Update National Research Summit on Care, Services and Supports for Persons with Dementia and Their Caregivers	[HTML Version] [PDF Version]

Videos

Welcome thru Perspectives	[Video]
Rachel, Jessica, George Presentations	[Video]
Keith Presentation and Panel Discussion	[Video]
Public Comments	[Video]
Care Summit and Milestones	[Video]
Federal Workgroups and Adjourn	[Video]

Last Updated: 06/29/2018