

Research to Clinic: ***Alzheimer's Disease Participation in Clinical Trials***

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Alzheimer's Association



OUR VISION:

A world without Alzheimer's disease®.

OUR MISSION: To eliminate Alzheimer's disease through the advancement of research; to provide and enhance care and support for all affected; and to reduce the risk of dementia through the promotion of brain health.

Outline

- Landscape of Alzheimer's disease
- National Plan to Address Alzheimer's
- Challenges to Clinical Study Research
- Examples of Tools to Support Raising Awareness of Clinical Studies
- National Strategy for Recruitment discussions
- Next Steps

Alzheimer's Epidemic Continues to Grow...

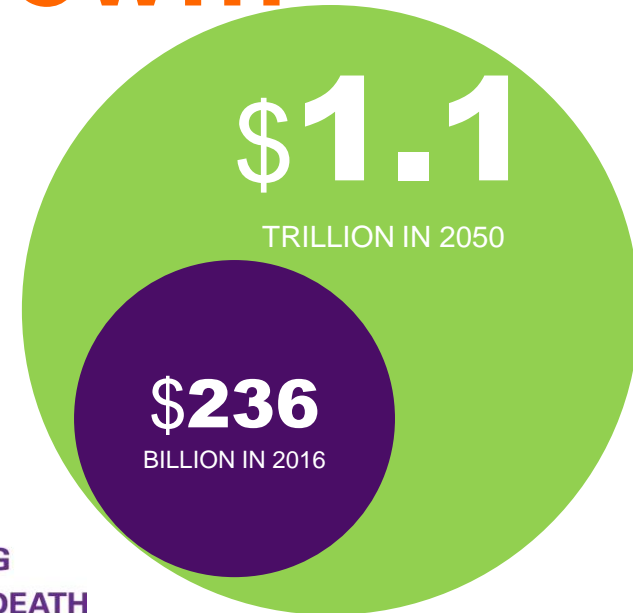
5.4

million Americans of ALL ages
will have Alzheimer's in 2016

6

Of the top 10 killers,
Alzheimer's is the
only one that cannot
be prevented, cured
or even slowed.

TH LEADING
CAUSE OF DEATH
IN THE U.S.



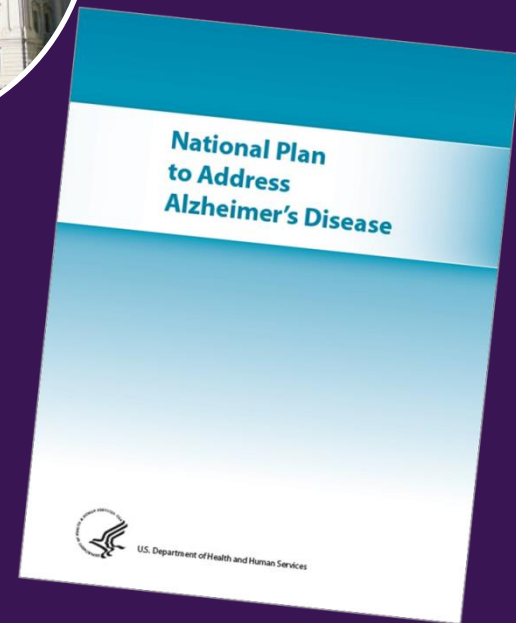
Total cost of care for those with Alzheimer's,
with more than two-thirds paid by Medicare and Medicaid

Source: Centers for Disease Control and Prevention (cdc.gov/nchs/fastats/leading-causes-of-death.html)



National Plan to Address Alzheimer's disease

“Increase enrollment in clinical trials and other clinical research through community, national, and international outreach”
(Strategy 1.B.3)



Challenges in Advancing Clinical Research



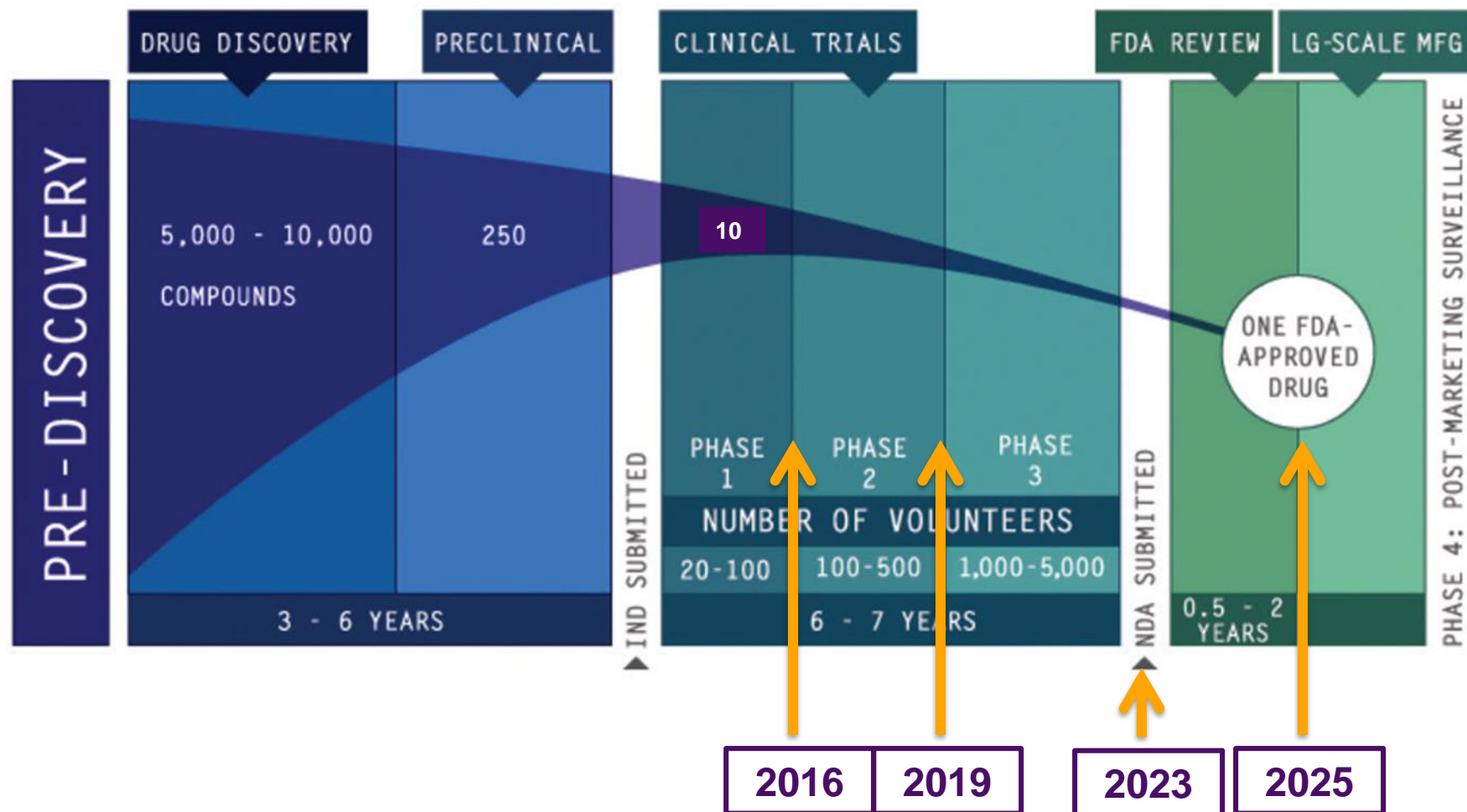
Funding



Recruitment

Pathway to Approval

Drug Discovery and Development: A LONG, RISKY ROAD



Challenges in Clinical Study Recruitment


- 10-12 studies actively recruiting volunteers at any given time
 - 24 multi-center AD clinical trials showed that 11 trials required ≥ 1.5 years to complete enrollment and two trials longer than 3 years
- Often, volunteers are over age 65, likely to suffer comorbidities that may exclude them
 - Example: 72% of 3,470 people recruited were not eligible for trial




Low Trial Awareness is **KEY** barrier to Trial Recruitment

Table 1. Barriers to AD trial recruitment.

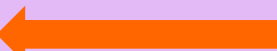
Patient-related barriers

- Low trial awareness 
- Comorbidities (e.g. excluded conditions)
- Polypharmacy (e.g. excluded medications)
- Availability of a study partner
- Attitudinal barriers (e.g. fear of randomization to placebo)

Caregiver/Study partner-related barriers

- Low trial awareness 
- Burden of care
- Logistical challenges (e.g. missing work)
- Financial challenges (e.g. cost of travel to site)
- Attitudinal barriers (e.g. fear of patient injury)

Physician-related barriers

- Primary care doctors have low awareness 
of trials and rarely refer

Current Landscape of Clinical Studies

- Today, 150 ongoing trials listed in clinicaltrials.gov in need of 70,000 volunteers (ADEAR)
- TrialMatch lists 265 ongoing trials actively recruiting
- This number will only grow in the coming years
- Increasing numbers of trials seeking asymptomatic volunteers (ADNI3, A4, EMERGE, ENGAGE, etc.)



Accelerating Recruitment to Alzheimer's disease Clinical Trials

Conducting more Ph3 trials in earlier stages of disease

High Screen Failure Rate

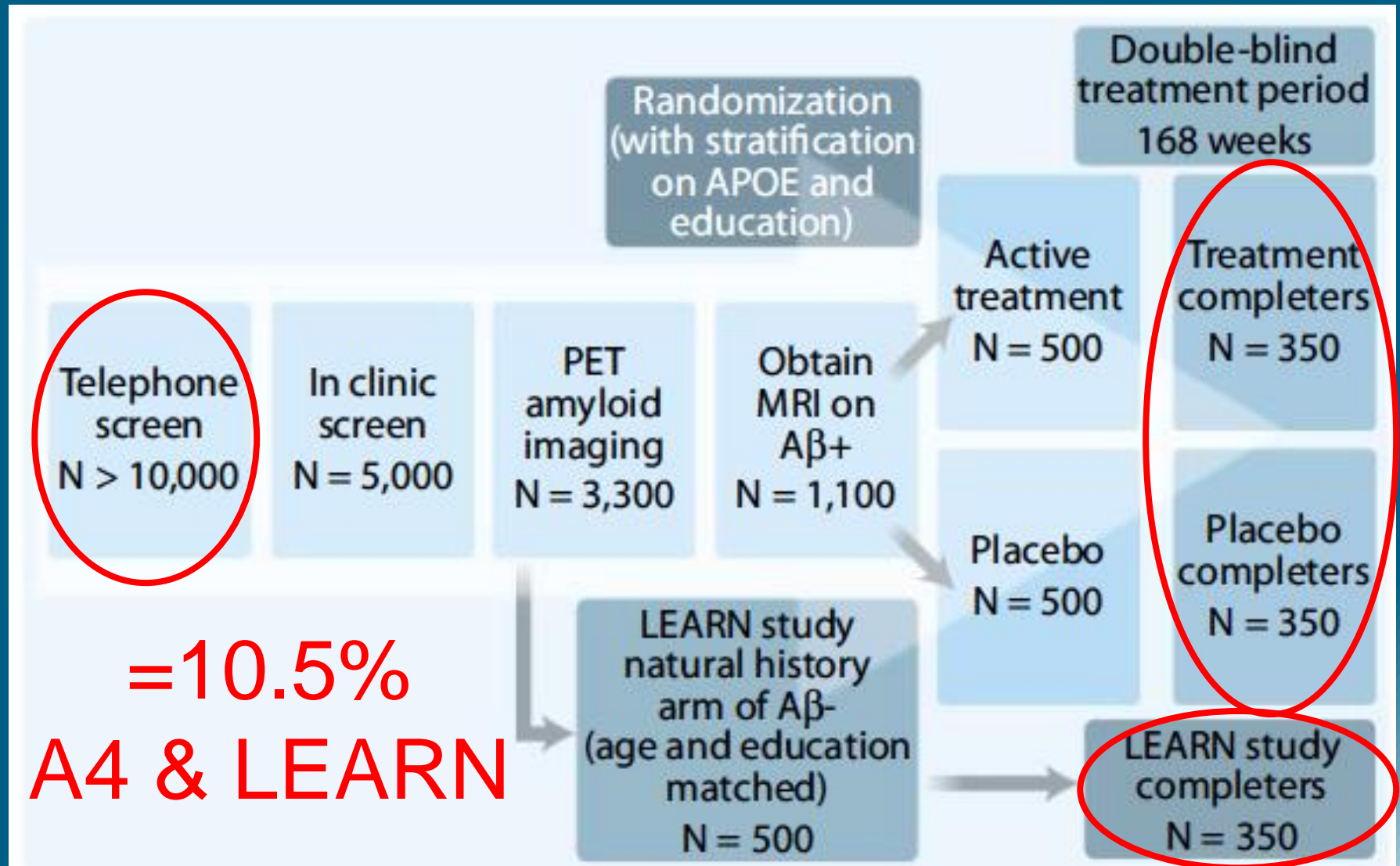
70-90%

**Many Ongoing
Clinical Trials**

**>50 ongoing Ph3 trials*
Average # patients = 982**

*clinical trials.gov

Challenges of Rapid and Efficient Recruitment and Screening for A4 Prevention Trial



Reference: Sperling R et al *Sci Trans Med* 2014

Examples of Tools to Support Trial Awareness/ Enrollment



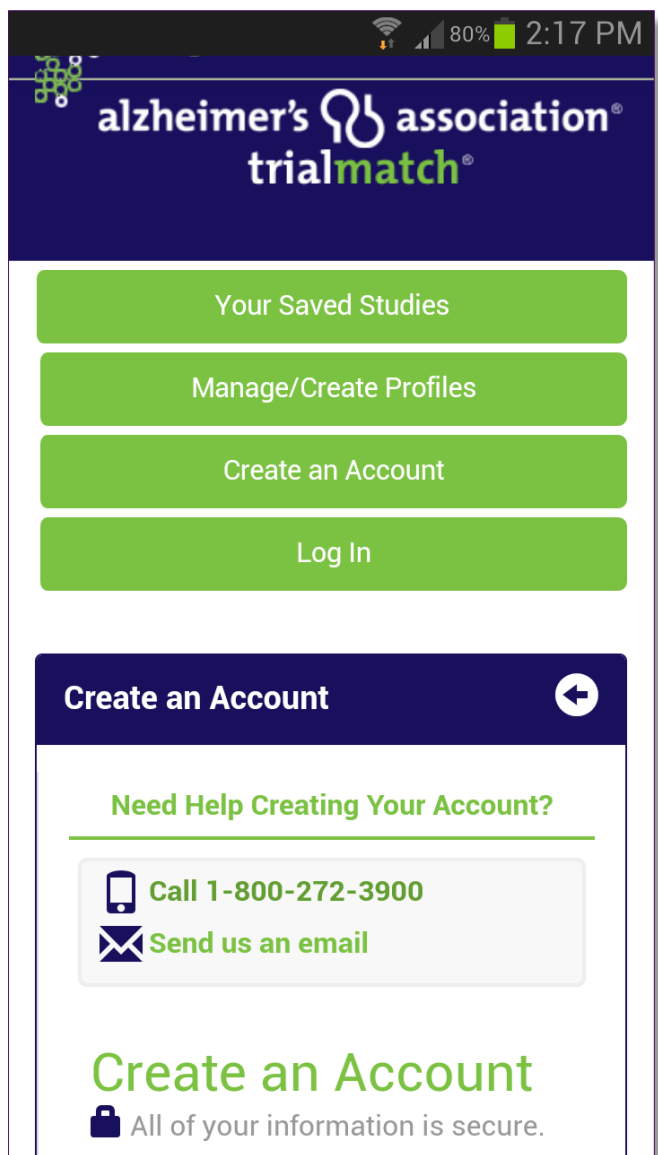
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190,000+
user profiles

250+
studies

alz.org/trialmatch



BrainHealth R E G I S T R Y

www.BrainHealthRegistry.org

- **A UCSF-based, online registry and cohort for recruitment, screening, and longitudinal monitoring**
- **Currently includes**
 - Over 51,000 consented participants, including many eligible candidates for Alzheimer's trials
 - Longitudinal data from over 44,000
 - Over 10,000 have been referred to clinical Alzheimer's research studies
 - Over 700 have been enrolled in clinical Alzheimer's studies (observational and intervention)
- **Methods for facilitating clinical Alzheimer's research**
 - Referral of current BHR participants to studies (industry and academic)
 - Prescreening using longitudinal BHR database (questionnaires and online cognitive tests)
 - Co-enrollment in BHR and other studies, such as ADNI and IDEAS, with data sharing
 - Development of algorithms to enrich for amyloid positivity and other AD risk factors
- **The BHR cohort itself is a large, observational study that can be used to test hypotheses; de-identified data is broadly shared**

How It Works

Register, consent online

Self-reported health history, family history, medications, memory problems, mood, lifestyle

Online cognitive tests

Study Partner can separately register and answer questions about participant and self

Participants and study partner return every 6 months to complete follow-up tasks

1

Sign up

2

Tell us about yourself

3

Take some tests

4

Invite a study partner

5

Come back...and come back again

www.endALZnow.org website



ALZHEIMER'S
PREVENTION
REGISTRY

HOSTED BY **BANNER ALZHEIMER'S INSTITUTE**

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ALZHEIMER'S
PREVENTION
REGISTRY

1

Sign Up to help end Alzheimer's

2

Receive Emails about prevention study opportunities and research news

3

Participate in studies you choose and qualify for

258,197

people have signed up to
help end Alzheimer's.

THE NEXT STEP IS YOURS.

→ **E-mail ***

→ **First Name ***

→ **Last Name ***

United States

→ **Zip/Postal Code ***

Year of Birth *

SIGN UP NOW ▶

[Already Registered?](#)

Your privacy is extremely important! We promise to protect it - [learn more](#)

Alzheimer's Prevention Registry

www.endALZnow.org

Who

- Anyone age 18 and older

Where

- Anywhere in the world; initial outreach has been focused in the United States

What & How

- Provide email address, other demographic & contact information at sign up
- Information is kept confidential and secure
- Receive emails with study opportunities, research news

Clinical Trial Recruitment Stakeholder Meeting at AAIC 2016

- **Proposed Goals from Stakeholder Discussion:**
 - **Near-term:** National campaign on importance participating in clinical trials
 - **Long-term:** Expert workgroup to consider sustainable structural solution options and present thought process to stakeholders



Long Term: Infrastructure/ capacity challenges?

- Are there site bottlenecks to enrolling participants?
 - Is this trial dependent (i.e. population being recruited)?
 - What is the contribution of IRB?
- Will sites be able to accommodate increased traffic of potential participants?
 - Is this really a concern?
 - If yes, What are barriers preventing sites from building increased capacity?



Stakeholder Discussion Recommendations

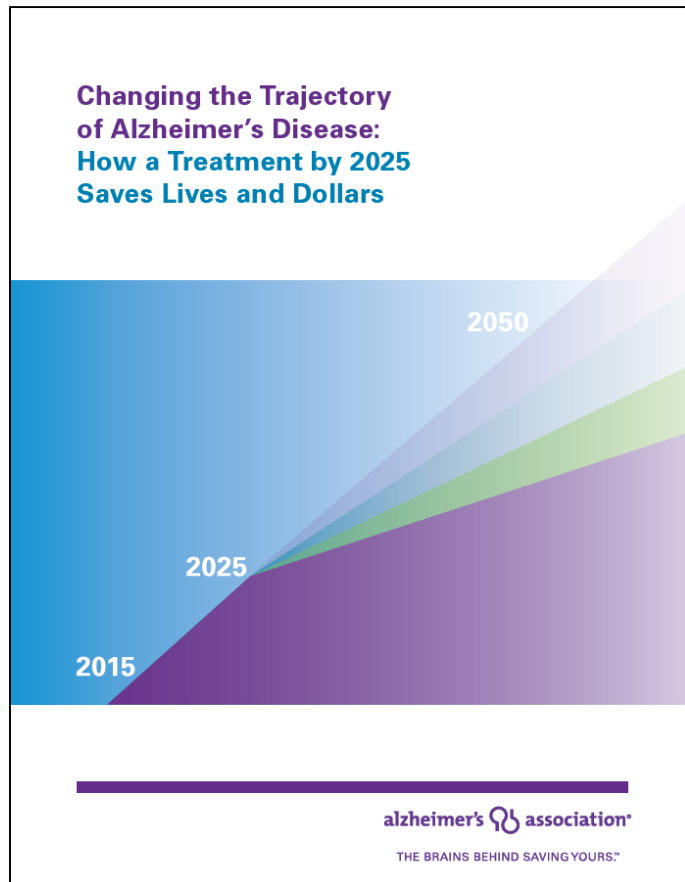
- Target audience: diverse aging populations
- Focus on underrepresented populations
- Messaging needs to be developed by multiple stakeholders (public, private/ non-profit, industry)
- Open source tools for recruitment; identify recognizable brand and broadly used by the field to engage participants

Recommendations – Next 6 Months

- Agreed to form small team of representatives
- Develop plan or strategy to address these challenges and present by April 2017 at NIA hosted open meeting
- GOAL: Harness ongoing energy and efforts to create unified plan of action and include key absent stakeholders



If we delay onset of Alzheimer's by 5 years...



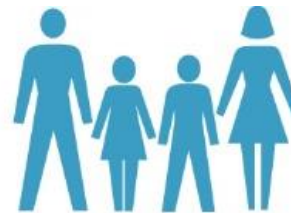
DELAYED ONSET

If we develop a treatment by 2025 that delays the onset of Alzheimer's by just five years, then:



5.7
MILLION

people expected to develop Alzheimer's **would not in 2050.**



Families
would save
\$87 billion in 2050.



In total,
America would save
\$367 billion in 2050.

What Can You Do Now?

- Talk about your experience Alzheimer's disease
- Participate in Longest Day or Walk to End Alzheimer's
- Talk to your legislators
- Support research - join a clinical study
- Maintain overall health – physical, mental and social



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Conclusions

- Alzheimer's disease is the 21st century health epidemic
- National Plan raises Alzheimer's to priority
- Challenges in clinical study recruitment
- Tools available to you to be more informed
Larger effort to help raise awareness,
address barriers and advance studies faster
- **You** can make a difference!
- More info at **alz.org**

THE END OF
ALZHEIMER'S
STARTS
WITH YOU

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