

Development and use of registries to accelerate enrollment into Alzheimer's trials

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Current Landscape in the United States

- In 2014, ~70,000 participants need to fill 150 Alzheimer's disease (AD) trials
 - Requires screening **minimum** 10x as many participants
- Anticipate a rapid upturn in the number of AD trials in the coming years
 - Particularly in hard to recruit populations (healthy older adults at risk for AD, MCI, mild/prodromal AD patients)
- At the same time, recruitment for trials face obstacles, approximately:
 - 85-90% of all studies have delays in recruitment
 - 30% of studies under enroll
 - Only 7% of studies meet enrollment goals in the originally stated timelines
 - Under enrollment of African Americans & Hispanic/Latinos in studies limiting generalizability of trial findings

Why a Registry?

- Ability to have thousands of interested individuals available to be contacted for a given study
 - GAP has estimated ~7 million adults need to be contacted in order to enroll 4,500 participants!
- Potential to reduce screen fail rate
- Potential to accelerate enrollment into trial, perhaps enhance retention of trial participants
- Online registry can complement and enhance local, grassroots recruitment effort and may be more cost-effective / efficient
- Depending on registry's design, may be able to leverage run-in data for trial

Challenges to Developing Recruitment Registries – Just the tip of the iceberg!

- If you build it, it does not necessarily mean they will come!
 - Why join if you are healthy?
 - And those who do join are predominately white, educated & female. Lack of “best practices”
 - how much data do you collect at signup? Different thresholds of commitment at entry yield different populations, results.
- Requires a high level of customer service and continued engagement
 - Reason why API is still only in English
- Ethics committee / IRB constraints and HIPAA constraints for sharing participant information with enrolling studies/sponsors → APR is creating “StudyMatch” platform
 - Complicated legal landscape in the US when DNA collection is added
- Creating IT infrastructure is time consuming and expensive; no perfect “out of the box” solution
- Model in US may need adaptation for ex-US
- Funding

Motivators and Barriers to Joining a Registry

- We conducted a national survey in 2012 (1024 US adults) and in 2014/15 analyzed nearly 19,000 conversations from 84 online destinations to try to understand the primary motivators and barriers for joining a registry and participating in trial
 - High interest in learning more about registries
 - Drivers include helping future generations, driving science forward, taking control of their own lives
 - Barriers include concerns regarding privacy/confidentiality, data security, who is “behind” the program

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



ALZHEIMER'S
PREVENTION
REGISTRY

www.endALZnow.org website



ALZHEIMER'S
PREVENTION
REGISTRY

HOSTED BY BANNER ALZHEIMER'S INSTITUTE

[Home](#) [About Us](#) [Press](#) [For Researchers](#) [Contact Us](#)

[Why Join](#) [Find a Study](#) [Spread the Word](#) [Alzheimer's Prevention 101](#) [About the 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

259,141 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](#)

WHY NOW?

Scientists are making great progress in the fight against

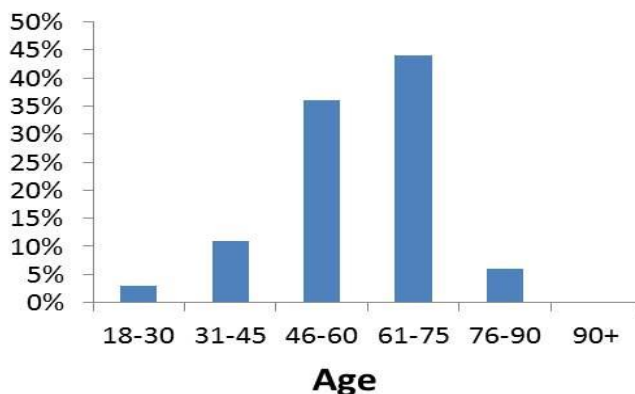
**THE ALZHEIMER'S PREVENTION
REGISTRY IS A PARTNERSHIP OF:**



ALZHEIMER'S
PREVENTION
REGISTRY

Enrollee Demographics

As of January 15, 2017 more than 255,000 enrolled



- 81% of enrollees are female
- 70% self-report a family history of Alzheimer's or other dementia
- 90% self-report not having a diagnosis of a cognitive impairment

Alzheimer's Prevention Registry

How much information are people willing to give
about themselves?

And can we use that information to help match
them to studies?

GeneMatch: A new program of the Alzheimer's Prevention Registry



ALZHEIMER'S
PREVENTION
REGISTRY
GeneMatch

Eligibility requirements:



Between 55 and
75 years old



Live in the
United States

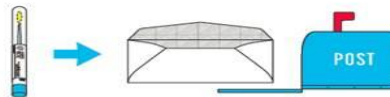


Do not have
diagnosis of
cognitive
impairment

-> endALZnow.org/genematch

GeneMatch: A program of the Alzheimer's Prevention Registry

- Participants sign up on the website (www.endALZnow.org/genematch):
 - Review brief, online education module (video or bulleted text)
 - Create a GeneMatch account
 - Electronically sign an informed consent
 - Provide demographic information
- Participants receive a cheek swab kit in the mail approximately 2 weeks later
- Participants complete the cheek swab at home and send it back in a pre-paid postage envelope along with the laboratory requisition form to the lab



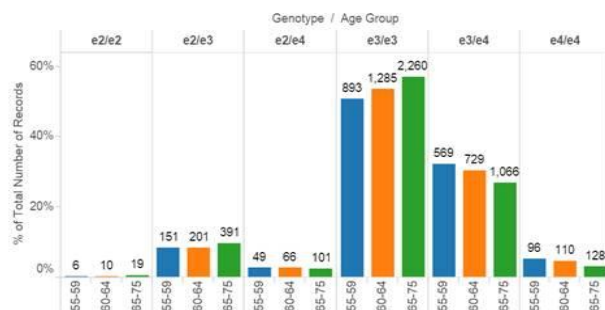
- CLIA-certified lab analyzes the swab and genetic information is stored in a secure database not viewed or accessed by GeneMatch staff
- GeneMatch does NOT disclose genotype results to participants
 - APOE genotype is used to help match people to study opportunities

GeneMatch Partner Sites

- Numerous Generation Study Sites are GeneMatch partner sites (aka, performance sites)
 - Requires institution to approve WIRB as IRB of record and site investigator as program sub-I
 - Not all institutions are willing to opt-in, with varying points of resistance
 - Allows for buccal swab kits to be distributed and completed on-site
 - Benefits:
 - Reduces time between enrollment and when APOE results are in the database
 - Allows sites to boost GeneMatch enrollment in their catchment area

GeneMatch Metrics

31,149 enrolled as of January 24, 2017



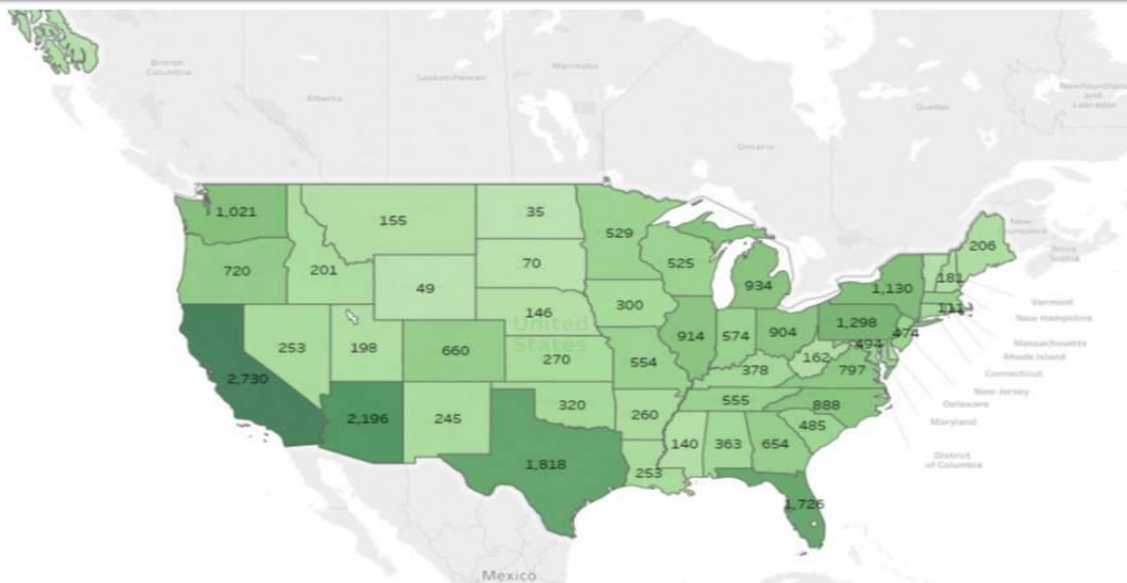
GeneMatch Participant Demographics:

- 70% female
- ~4-5% APOE ε4/ε4
- ~30% APOE ε3/ε4

Promoting the API Generation Study to GeneMatch members:

- 264 invited to the study
- 123 accepted their invitation
- 1 declined

GeneMatch – Enrollment by State (as of 16-January 2017)



Confidential — do not copy, distribute or use without prior written consent.

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Facebook Advertising: 2016 Success Story

- Over 16,000 new GeneMatch members in Q4 2016
 - The result of targeted Facebook campaign
 - 21% of people who clicked on an ad completed the GeneMatch enrollment process
 - The most successful creative concepts were those that utilized social pressure and those that contained elements that have been shown to drive high click-through rates (i.e. polling boxes)
 - Average cost \$2.88/enrolled

GeneMatch – 2016 Advertising

Alzheimer's Prevention Initiative
Sponsored (demo) · Like Page

Scientists need your help to end Alzheimer's! If you're between the ages of 55 and 75, you could be a part of a program that aims to end the disease before it impacts another generation. Be among the 30,000 people taking part in research through the GeneMatch Program. Learn more today: <http://bit.ly/2gQ77Mz>



WITH YOUR HELP, WE CAN END ALZHEIMER'S.
Join the 30,000 people taking part in an Alzheimer's program.

Learn More About the GeneMatch Program Today
www.endALZnow.org/genematch
ENDALZNOW.ORG

603 · 60 Comments · 473 Shares

Alzheimer's Prevention Initiative
Sponsored (demo) · Like Page

Without your help, the number of Americans with Alzheimer's may increase to over 15 million by 2050 – more than triple the number affected today! If you're between the ages of 55 and 75, you could be a part of a program that aims to end the disease before it impacts another generation. Get started today: <http://bit.ly/2fG1HyB>

Ready to be a part of a study that could end Alzheimer's?
SELECT YOUR AGE TO GET STARTED:

☐ 55-59 ☐ 60-64 ☐ 65-69 ☐ 70-75

Learn More About the GeneMatch Program Today
www.endALZnow.org/genematch
ENDALZNOW.ORG

171 · 15 Comments · 128 Shares

Potential Solutions

- Increase participation of underrepresented populations
 - Overhaul of content and messaging to ensure clear, accessible language
 - More approachable for low literacy English speakers, which will likely enhance usability for higher-literacy users
 - Translate content into other languages, starting with Spanish
- Development of a repository for screen failed participants
 - Not sponsor specific
 - Contains reasons for screen fail (e.g., SUVR value \neq amyloid positive) and ability to re-contact participants for other studies
- National IRB oversight of registries, willingness to approve motivational (not overpromising) messaging. Examine HIPAA constraints and potential solutions
- Federal funding for registries that provide a shared recruitment resource

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]

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