

## ALZHEIMER'S PPRN

Patient & Caregiver-powered Research Network

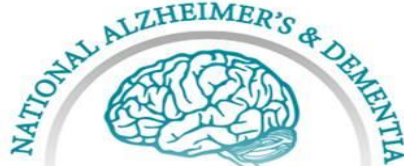
### **Strategies to facilitate recruitment and screening for Alzheimer's clinical trials**

HHS NAPA Advisory Council for Research, Care and Services  
February 3, 2017

Rachel L. Nosheny, Ph.D.  
UCSF Department of Radiology and Biomedical Imaging  
Co-investigator



University of California  
San Francisco



## ALZHEIMER'S PPRN

Patient & Caregiver-powered Research Network

**Funded by:**



**pcornet**

The National Patient-Centered  
Clinical Research Network

**A collaboration between:**



**BrainHealth**  
REGISTRY

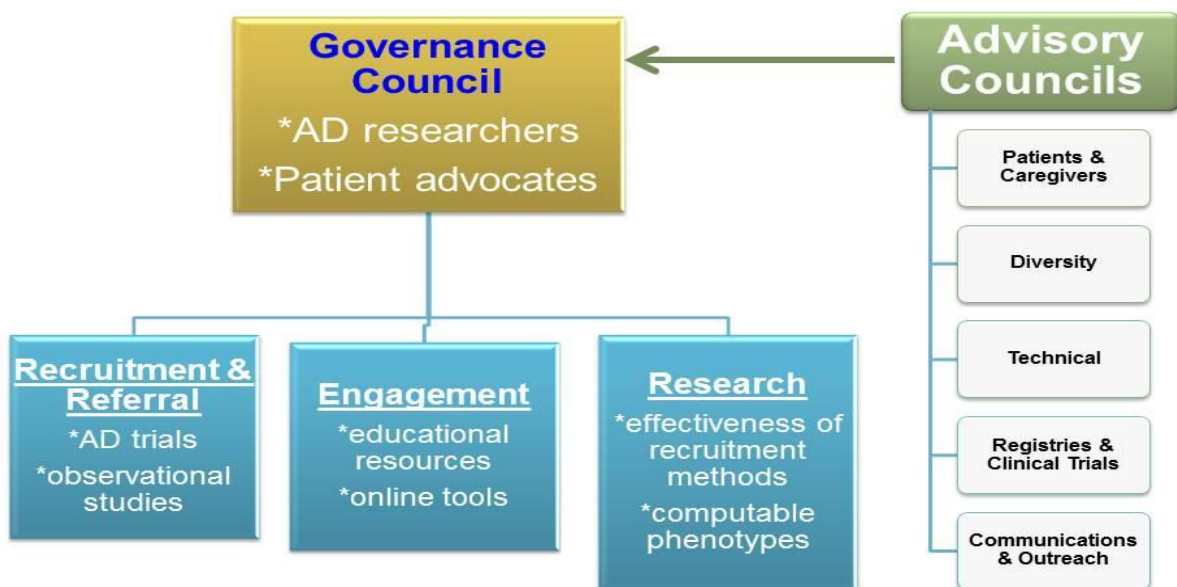
**Leadership:**

- **Principal Investigator** ▶ **Ron Petersen, Mayo Clinic**
- **Co Investigators**
  - ▶ Meryl Comer, Geoffrey Beene Foundation
  - ▶ Michael Weiner, UCSF, Brain health Registry
  - ▶ Glenn Smith, University of Florida
  - ▶ Alex Alexander, Mayo Clinic

## AD-PCPRN Goal and Specific Aims

- **Overall goal:** To accelerate development of effective treatments for Alzheimer's disease and related dementias
- **Specific Aims**
  - ▶ **Connect** patients, caregivers, and researchers focused on developing, conducting, and disseminating patient-centered dementia research
  - ▶ **Recruit, engage, and educate** individuals at risk for or with Alzheimer's Disease and related dementias and caregivers in a patient-centered network
  - ▶ **Screen, refer, and enroll** individuals in Alzheimer's trials and observational studies
  - ▶ **Increase diversity** in Alzheimer's trials through outreach to minority populations, especially African Americans and Latinos

## AD-PCPRN Structure



# BrainHealthRegistry.org: Web portal for recruitment, engagement & longitudinal monitoring

The screenshot shows the homepage of BrainHealthRegistry.org. At the top, there is a navigation bar with links for HOME, NEWS, VIDEOS, PAGES, CONTACT, DONATE, and LOG IN. Below this is the BrainHealth Registry logo and a secondary navigation bar with links for HOW IT WORKS, WHY IT MATTERS, and WHO IS INVOLVED. The main content area features a large banner with the text "ANSWER QUESTIONS & TAKE TESTS" and a sub-headline: "When you complete online brain tests, we get 'snapshots' of your health and brain performance. With many snapshots, from you and others, we can make a huge difference." Below this is a "See How It Works" link. Further down, there is a section titled "It's safe, easy and free." with a "JOIN NOW" button and a link for "Already a member? Log in here". Three news items are displayed: "Side By Side With B. Smith In Her Alzheimer's Fight", "New partnership to study link between olfaction and neurodegenerative...", and "Draymond Green Supports Brain Health Registry". The footer contains a "For Investigators" link, a "PRIVACY" link, copyright information for 2010-2018 The Regents of the University of California, and logos for BrainHealth and UCSF.

## Brain Health Registry: How It Works

Register, consent  
online

1

Sign up

13 questionnaires  
(health history, family  
history, medications,  
memory problems,  
mood, lifestyle)

2

Tell us about yourself

3 Online cognitive  
tests

3

Take some tests

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

4

Invite a study partner

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

5

Come back...and come back  
again



## AD-PCPRN participants in the Brain Health Registry

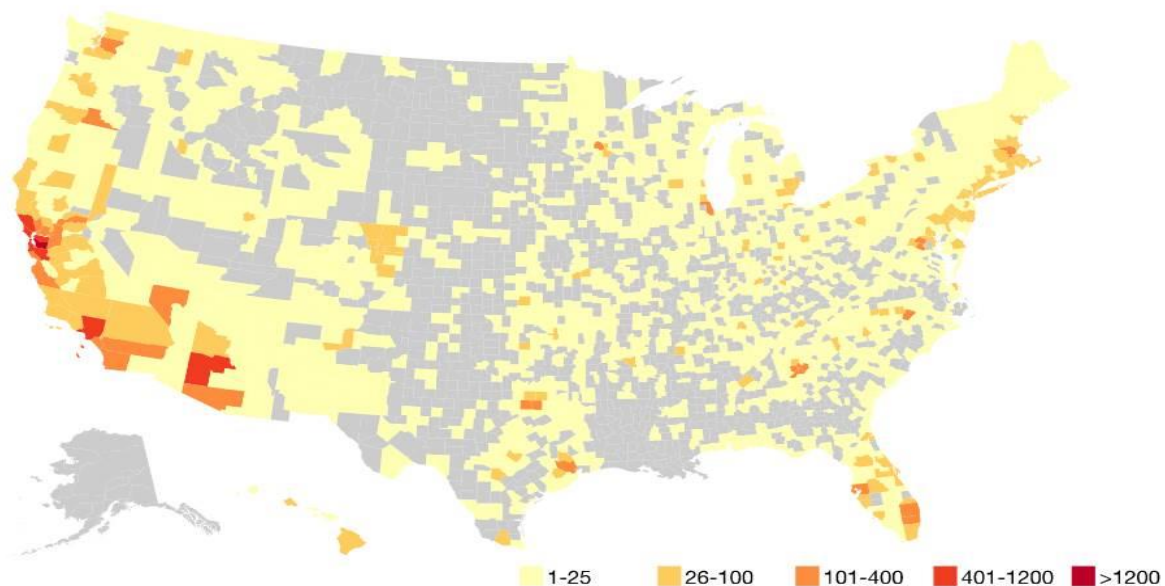
### ■ Total of **30,944** participants enrolled

- ▶ Age 55+
- ▶ Interested in learning about future research opportunities

### ■ Longitudinal data collected from **12,975**

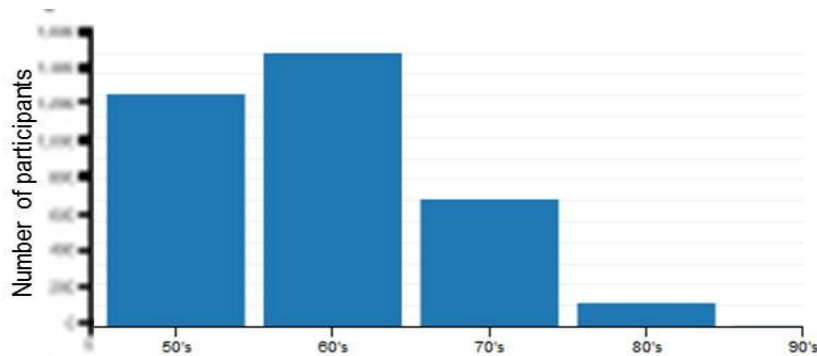
- ▶ Retention rate of ~40% over 2 years of follow up
- ▶ 31% complete all tasks
- ▶ 64% provide enough information to assess whether they are likely to be eligible for AD trials

## Geographic distribution of participants

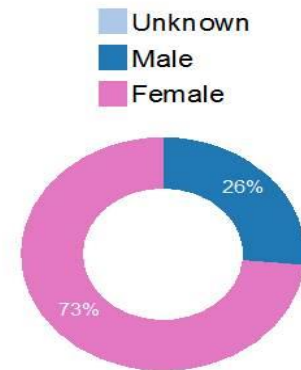


## Demographics

### Age Distribution

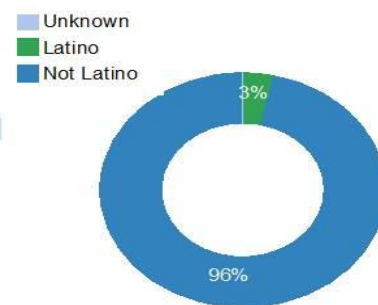
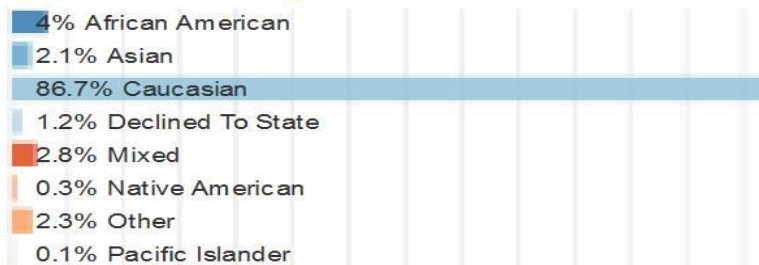


### Gender

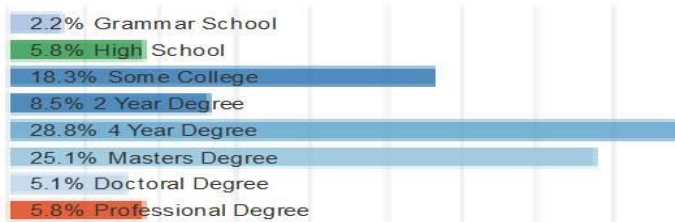


## Demographics

### Race & Ethnicity

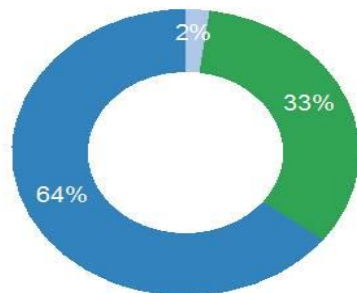


### Educational Attainment

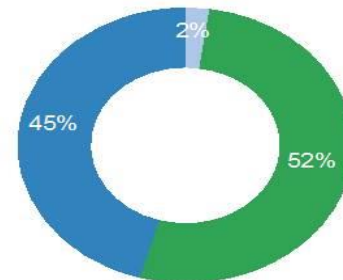


## Alzheimer's risk factors

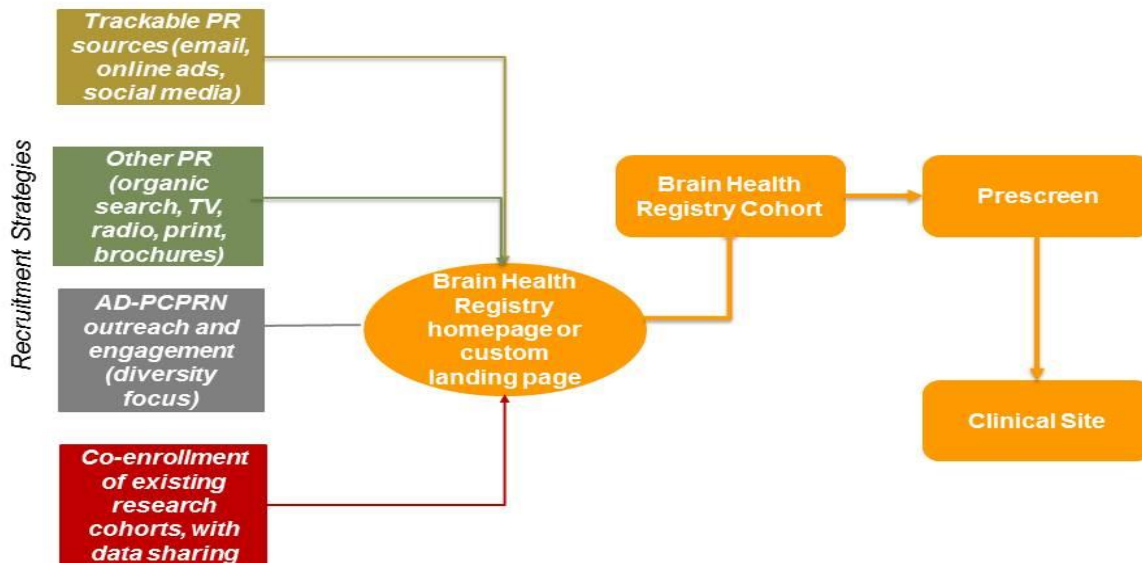
### Family History of Alzheimer's



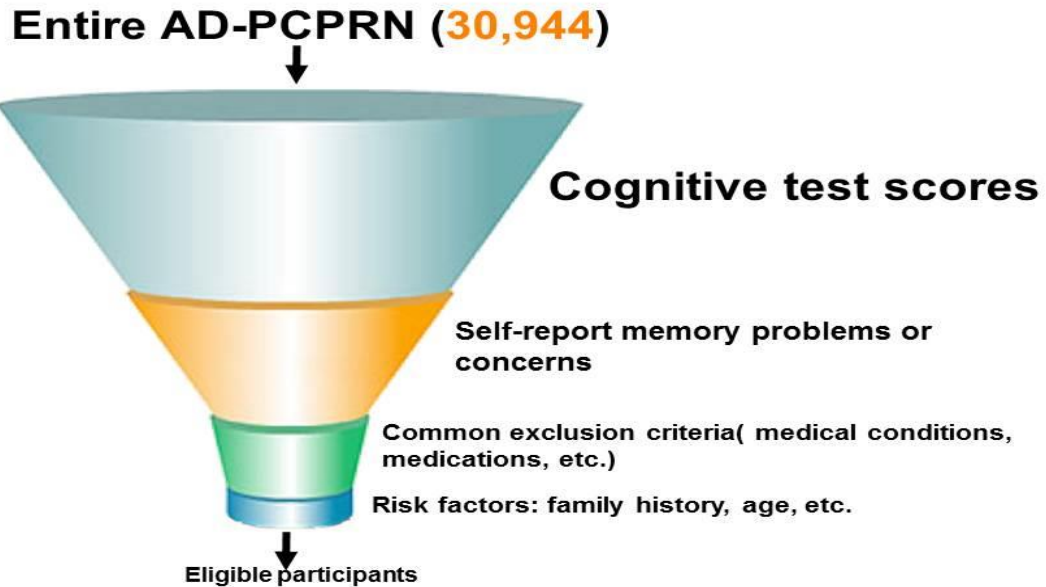
### Memory Concern



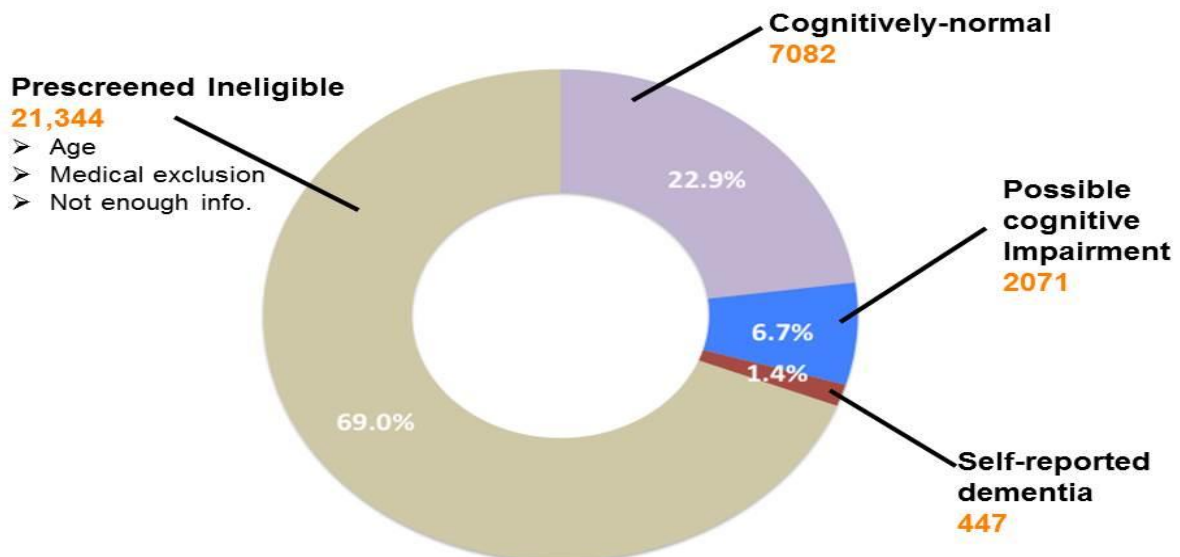
## How does the AD-PCPRN facilitate AD clinical study recruitment?



## Prescreening participants for AD clinical trials



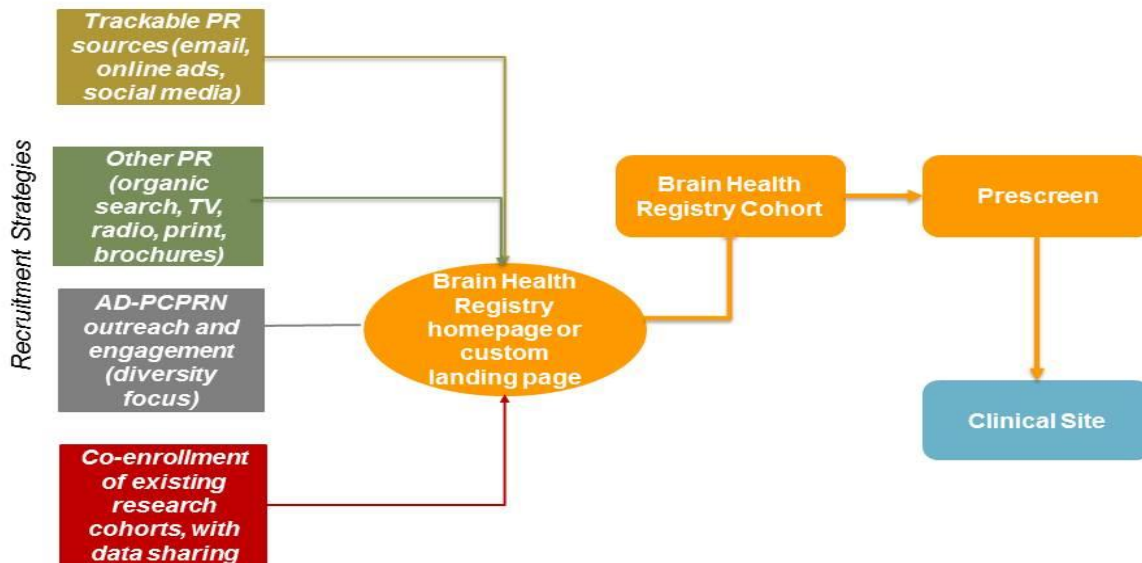
## ADPCPRN participants likely to be eligible for Alzheimer's trials



## Referral of AD-PCPRN participants to clinical studies

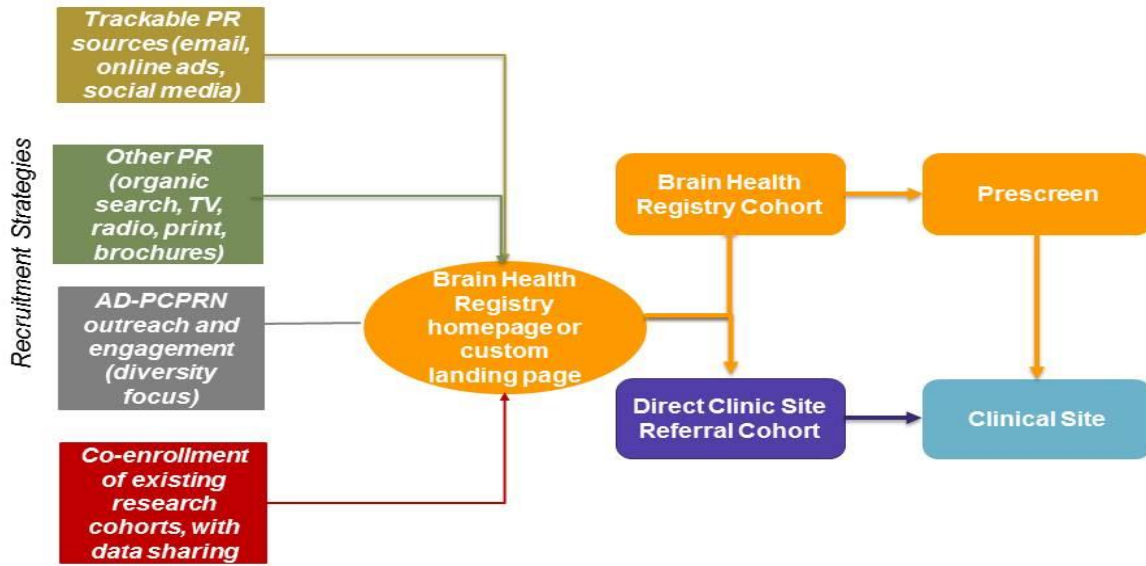
- **10,001** participants have been referred to **10 Alzheimer's and aging clinical studies**
  - ▶ Large, observational studies (late life depression, healthy aging, olfaction)
  - ▶ Randomized treatment trials
  - ▶ Validation study of online tests
- **757** participants have been enrolled in studies
  - ▶ Vast majority are enrolled in observational or validation studies
  - ▶ A major challenge has been to successfully enroll in treatment trials

## New strategies to maximize enrollment in trials

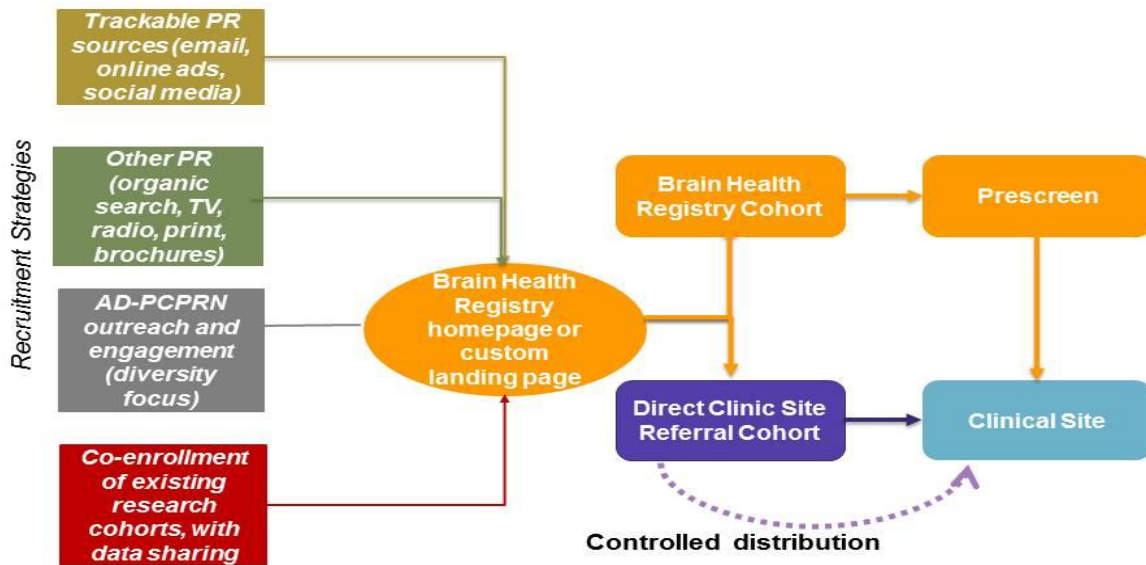




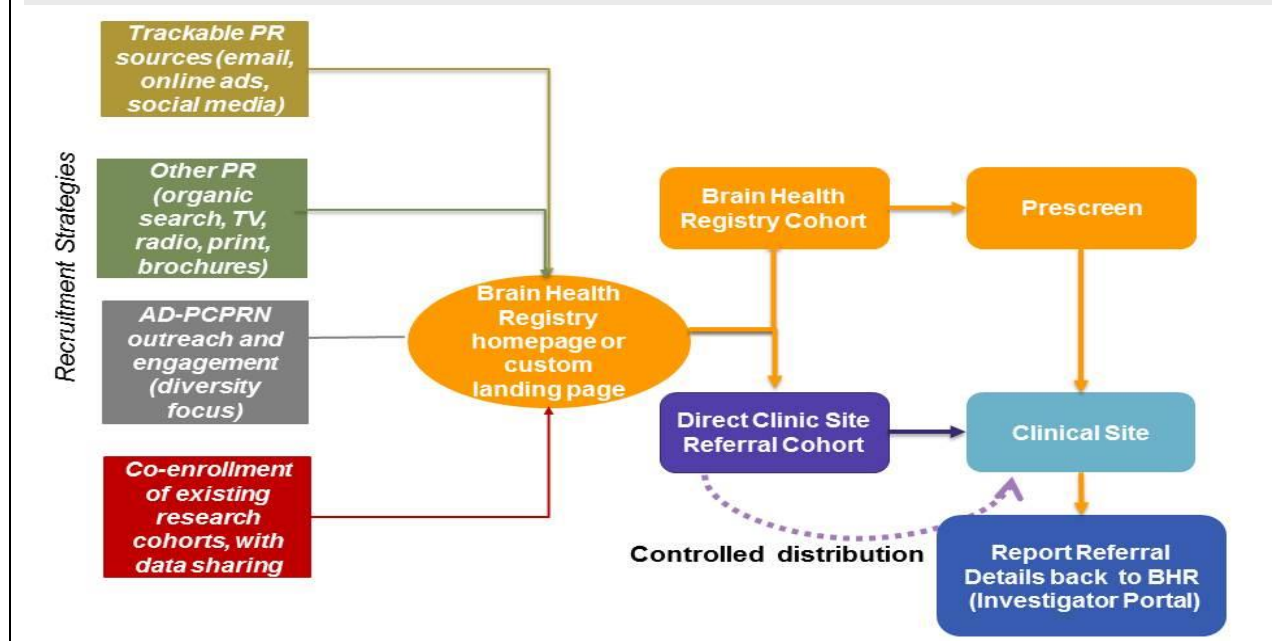
# New strategies to maximize enrollment in trials



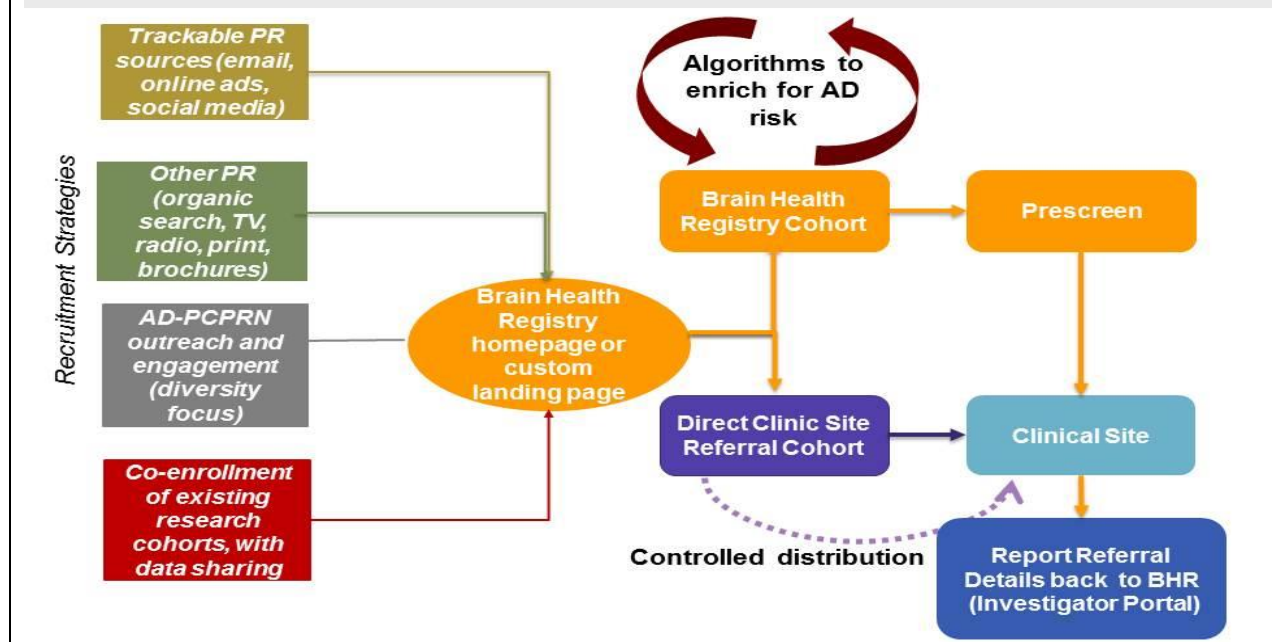
# New strategies to maximize enrollment in trials



## New strategies to maximize enrollment in trials



## New strategies to maximize enrollment in trials



## Facilitating recruitment through study partner engagement: The Brain Health Registry Caregiver & Study Partner Portal

HOME STUDIES NEWS VIDEOS FAQs DONATE LOG IN



HOW IT WORKS

WHY IT MATTERS

WHO IS INVOLVED

### Study Partner Portal

JOIN NOW



Welcome to the Study Partner Portal of the Brain Health Registry. This exciting new initiative allows you and your study partner to work as a team to advance brain health research and the search for new treatments.

#### Why are we asking you to become a study partner?

Put simply, we are committed to advancing brain health research for all, and you are a powerful part of that plan. [Click here](#) to join or, if you'd like more details about why, read on.

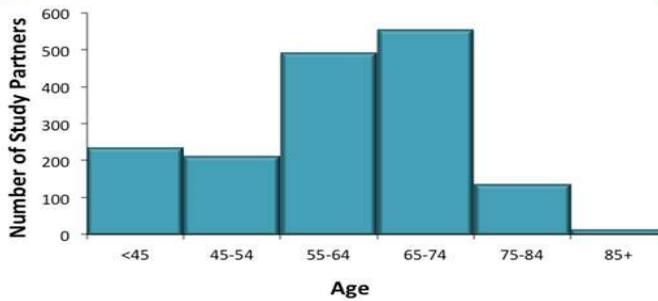
## Brain Health Registry Caregiver and Study Partner Portal (CASPP)

- Infrastructure & database within BHR for a study partner to separately register and consent online
- Study partners answer questions about the participant's cognitive and daily functioning
- Unique advantages of study-partner reported information
  - ▶ Associated with many disease-related outcomes
  - ▶ May sometimes be more accurate than self-report
  - ▶ Can identify change in function using a single data point
  - ▶ Focuses on outcomes that matter to patients & families
  - ▶ Can help overcome patient barriers to participation
  - ▶ May help recruit participants who are too impaired to join themselves
- Study partners also report on their own health and caregiver experience
  - ▶ Improve caregiver health

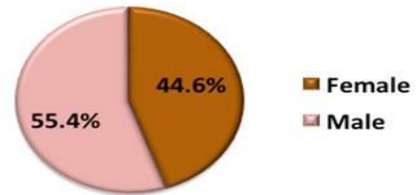
# Demographics of AD-PCPRN Study Partners

Total: **1895** Study Partners

## Age Distribution

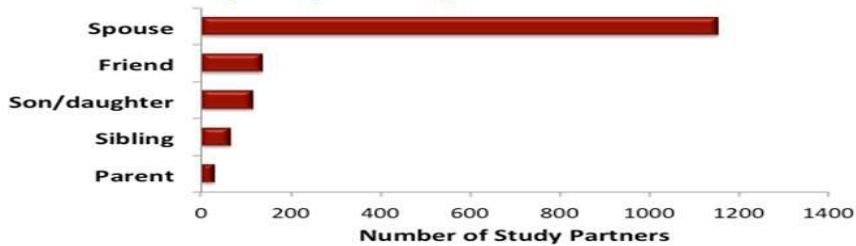


## Gender

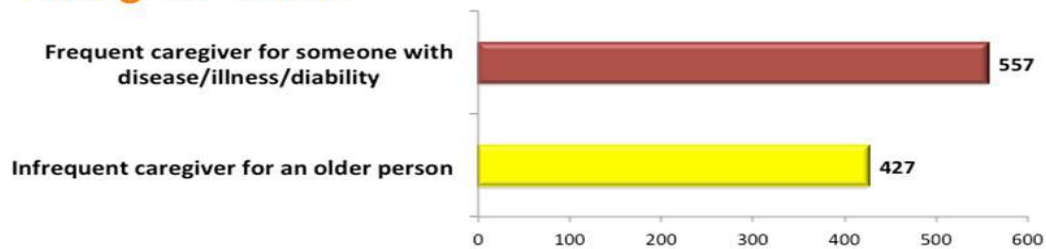


# Demographics of AD-PCPRN Study Partners

## Relationship to participant



## Caregiver status





## Characteristics of BHR Study Partners: Report of health/cognitive status

### About the participant

#### Report of participant status

Concern about participant memory	9.5%
Participant cognitive change	15.6%
Participant IADL change	10.5%
Participant MCI	2.0%
Participant AD	0.9%

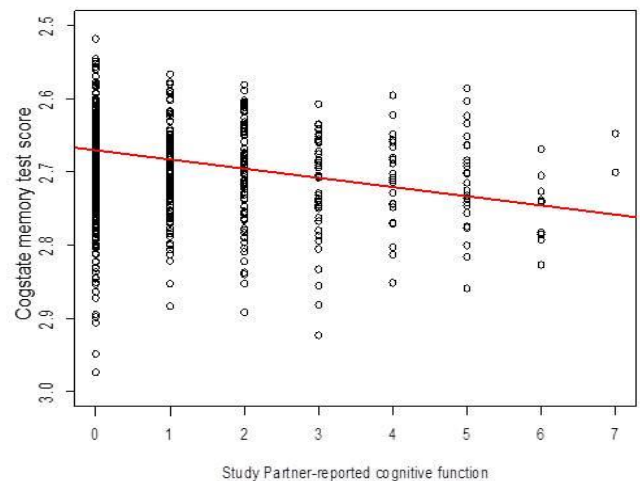
### About the study partner him/herself

#### Self-report health

Memory concern	34.7%
Positive stress screening question	6.3%
Positive mood screening question	15.4%

## Online study partner-reported data provides valid information about participant function

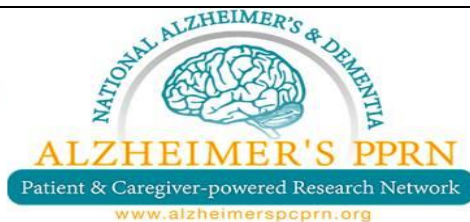
- Study partner-reported variables are significantly associated with:
  - ▶ self-reported subjective memory complaints
  - ▶ Self-reported recent changes in memory and daily functioning
  - ▶ Online memory test scores of the participant



Nosheny *et al* CTAD 2016

## Summary & Future Directions

- **Overall Goal** of the AD-PCPRN is to facilitate Alzheimer's clinical research
- **To date**
  - ▶ Over 30,000 participants, 1800 study partners, and 800 caregivers are enrolled in AD-PCPRN through the Brain Health Registry
  - ▶ Over 700 participants have been enrolled in clinical research studies
  - ▶ Engagement efforts are reaching many more, with a focus on increasing diversity
  - ▶ Major challenges are successful enrollment in to treatment trials and recruitment of minorities
- **In the future, the AD-PCPRN will aim to**
  - ▶ Increase enrollment and engagement of participants
  - ▶ Optimize referral to studies by analysis of success rates
  - ▶ Conduct research to advance recruitment science



### Partners



### Leadership

#### Principal Investigator:



Ronald C. Petersen,  
MD, PhD  
Mayo Clinic

#### Co-Investigators:



Alex Alexander,  
MBA, MPA  
Mayo Clinic



Meryl Comer  
Geoffrey Beene  
Foundation



Glenn Smith, PhD  
University of  
Florida



Michael W. Weiner,  
MD  
UCSF

**Governance Board:** all investigators +  
Debra Lappin, FaegreBD Consulting  
Rachel Nosheny, UCSF, Brain Health Registry  
Sally Sacher, Us Against Alzheimer's  
George Vradenburg, Global Alzheimer's Platform Foundation

## 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](mailto:napa@hhs.gov).

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### **General Information**

<b>Agenda</b>	<a href="#">[HTML Version]</a> <a href="#">[PDF Version]</a>
<b>Meeting Announcement</b>	<a href="#">[HTML Version]</a> <a href="#">[PDF Version]</a>
<b>Meeting Summary</b>	<a href="#">[HTML Version]</a> <a href="#">[PDF Version]</a>
<b>Public Comments</b>	<a href="#">[HTML Version]</a>

### **Handouts**

<b>Panelist Bios</b>	<a href="#">[HTML Version]</a> <a href="#">[PDF Version]</a>
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### **Presentation Slides**

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

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

## **Videos**

<b>Welcome thru Perspectives</b>	<a href="#">[Video]</a>
<b>Rachel, Jessica, George Presentations</b>	<a href="#">[Video]</a>
<b>Keith Presentation and Panel Discussion</b>	<a href="#">[Video]</a>
<b>Public Comments</b>	<a href="#">[Video]</a>
<b>Care Summit and Milestones</b>	<a href="#">[Video]</a>
<b>Federal Workgroups and Adjourn</b>	<a href="#">[Video]</a>

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Last Updated: 06/29/2018