

# National Recruitment Strategy

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Lessons Learned, Innovation and the Way Forward



## GAP Mission and Strategy

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- **Mission:** To reduce Alzheimer's clinical trial cycle times by up to two years
- **Strategy:**
  - Speed trial start-up through a standing, high performance network of certified trial sites utilizing standardized processes, contracting, staff training and national IRB
  - Increase volume and efficiency of participant recruitment across all trials, studies, sponsors, and disease stages
  - Build local capacity through community-based, site-centric program
  - Engage communities through integrated political, business, media and site systems
  - Embed clear minority recruitment goals and minority-friendly referral programs
  - Engage health systems and primary care physicians
  - Set clear site and network performance metrics ... measure ... innovate ... repeat



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# Improving Internet Recruitment Technology

- Conducted a year-long pilot with Brain Health Registry to test social media based recruitment campaign, measured in five markets
- Collecting data on cost of acquisition throughout recruitment process
- Identified impediments that led to planned improvements in both BHR and GAP digital strategies
- Finalizing development of GAP's digital approach – an open source, interoperable database embedded in site-centric, community based approach

Type of Member	# Members	Cost/Acquisition
Total BHR Membership/GAP	7,623	\$73
<b>Referral Candidates</b>		
# Possibly Impaired	233	\$2,403
# Cognitively Normal	843	\$664
Awaiting Cog Test Results	165	\$3,394
No Cog Tests	2,145	\$261
Total Potential for Referral	3,386	\$165
<b>Referred to Studies</b>		
Referred	1,711	\$327
Responded	342	\$1,637
Interested	209	\$2,679
Screened by Site Staff	90	\$6,222
Eligible	53	\$10,566
Enrolled	On-going	TBD

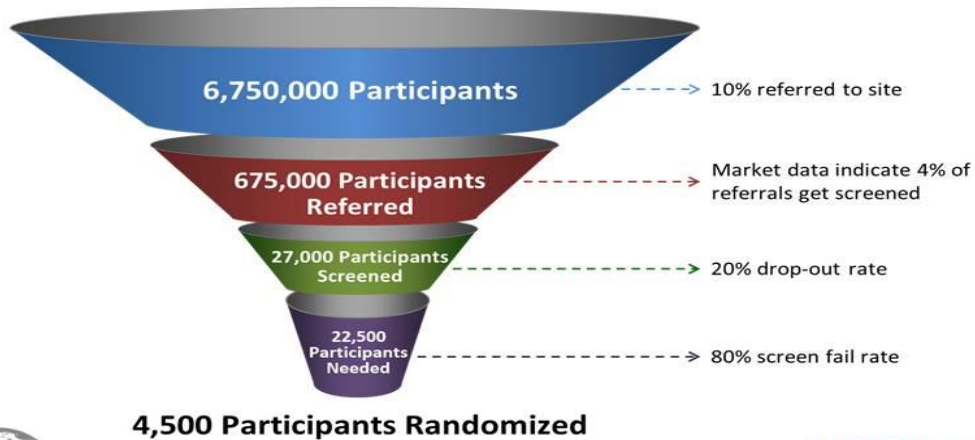


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# 2016 Economics of Recruiting Are Challenging

To recruit the estimated 4,500 participants needed for a range of oncoming preclinical/prodromal trials, if dependent on current Internet registry techniques, nearly 7 million people may need to be contacted



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## Approach

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### What is the nature and size of the problem?

- Set goals that 'fit' the problem
  - Size of participant population needed by stage of disease
  - Inclusive of minorities
  - Participant-oriented and participant-friendly
  - Sponsor, academic/commercial site and trial/study neutral
  - Ensure sites have the capacity to assess increased recruits in timely fashion
- Set tactics that are well-targeted and appropriately-scaled
  - Community and site centric – all recruitment is local
  - Performance and metric oriented
  - Collaborative—incentivize data sharing and interoperability of databases to improve participant access
- Innovate > measure > report > repeat



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## Investing in Local Research Sites

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- Invested \$100k in 11 pilot sites in GAP-Net site network
- Sites that hired a dedicated local recruiter for all trials saw an increased enrollment of nearly 43%
- Cost per randomized participant at pilot sites: \$1,500
- Investment in new initiative at KU yielded 160% year over year increase in referrals
- Other key impacts of investments:
  - Technology enhancements, including targeted recruitment via GIS
  - Specialized outreach/advertisements e.g., TV ads
  - Site participation in additional studies
- Network now includes 45 U.S. and Canadian sites (26 academic, 19 private)
- Sites must meet quality and performance metrics informed by pilot results



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## Novel Recruitment Approach

Site-centric, community-based approach: a collaboration between research sites, health systems, large local employers, and community leaders



## Role of Council: Integrating Efforts, Setting Goals

- **National challenge, national community-based response**
  - Patients want faster cures, communities feeling the pain, sites feeling the strain
  - Public and private sponsors and clinical researchers want greater capacity
  - Prevention trials present a particular challenge
  - Grow percentage of minorities participating in trials year-over-year
- **Integrate National Initiatives: ACTC, NCATS (RICS/TICS), National Recruitment Initiative, GAP**
- **Innovation goals:**
  - Key performance indicators: national trial capacity; cost/enrollment; number of participants in trials/studies
  - Increase number of AD trial participants to x% of estimated affected population (UK)
  - Expand application of technologies – including mobile – for trial recruitment and inclusion in protocols
  - Develop site-centric, community-based recruitment programs in 100 locations by 2020
- **Beyond Alzheimer's: Citizen Participation in Research**
  - 50% of American families participating in clinical research by 2025

## Need for Inter-Agency Collaboration

- **NIH** – Spearhead effort across Institutes (NIA, NCATS, NIMHD, NINDS); report and reward effectiveness of recruiting underrepresented populations
- **CDC** – Raise awareness of AD, early diagnosis, clinical research value ('first person cured of Alzheimer's will be in a clinical trial'); report concentration of AD patients by county
- **CMS** – Establish reimbursement guidelines (e.g., Star Ratings and HCC weightings) to incentivize physician assessment and support of research
- **FDA** – Foster innovation in clinical trial design; big data/biomarkers; give AD therapies breakthrough status
- **IHS** – Offer clinical trial resources to underserved Native American populations
- **VA** – Increase veterans' access to research opportunities



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The First Person Cured of Alzheimer's Will  
Be in a Clinical Trial

Thank You



## 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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