Engaging Participants in Precision Clinical Trials: Examples from Alzheimer’s Disease Prevention Trials

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Launched in anticipation of Alzheimer’s prevention clinical trials, serving as a pre-enrollment recruitment mechanism to identify potential study participants.

To date, enrolled >5600 PSEN1 E280A mutation kindred members in Colombia:
- 1173 mutation carriers
- 4420 kindred non-carriers
- Required considerable community outreach, review of church records, family meetings, and other outreach tactics.

All participants for the Alzheimer’s Prevention Initiative Autosomal Dominant Alzheimer’s Disease Trial were recruited from the Registry.
Example of a Successful Recruitment Mechanism: GeneMatch

• Launched in November 2015 as an online, trial-independent genetic recruitment registry for Alzheimer’s prevention trials in the US
  o [www.endALZnow.org/genematch](http://www.endALZnow.org/genematch)
• Participants are not told their APOE test results, but recruiting studies may require disclosure as part of screening/enrollment
  o Testing done by a CLIA certified / CAP accredited lab
• To date, enrolled >33,000 cognitively healthy adults ages 55-75
  o ~4% APOE ε4/ε4
  o ~30% APOE ε3/ε4
  o Required significant advertising, community outreach and talks
• Continued email engagement with participants is important since it may be months to years until they are matched to a trial
• Primary recruitment source in the US for the API Generation Study
Example of Recruitment Funnel for the API Generation Study

- General Population within age range ~58-74 years
- Genotyping (e.g. GeneMatch) (~100k-120k estimated)
- Consent for clinical study
- Eligibility Criteria
- Randomized (~600)

Estimated that 100k-120k GeneMatch completions are needed to randomize approximately 600 patients in the US.

Participants in age range are still active and may not have time to dedicate to a clinical trial.

Targeted population (APOE4 Homozygotes) are limited; Eligible participants can fail on cognitive assessments.
Thank you