

ALZHEIMER'S DISEASE CLINICAL TRIALS FACT SHEET

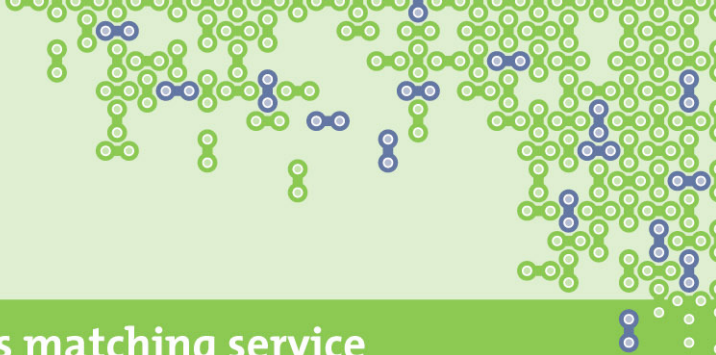
Why are clinical trials in Alzheimer's disease important?

Clinical trials are essential to advancing Alzheimer's disease research at a time when Alzheimer's is reaching epidemic proportions.¹ Through clinical studies conducted over the last 20 years, scientists have made tremendous strides in understanding how Alzheimer's affects the brain. More than 100 Alzheimer's clinical trials are now recruiting participants. Today, the field needs 50,000 volunteers, both with and without Alzheimer's, to participate.³ It is only through clinical studies that we will develop and test promising new strategies for treatment, prevention, diagnosis, and ultimately a cure for Alzheimer's disease.

Why are so many participants needed for Alzheimer's disease clinical trials, in particular?

The greatest obstacles to developing the next generation of Alzheimer's treatments are (1) inadequate funding for Alzheimer's research, and (2) recruiting and retaining clinical trial participants.³ In addition, there are challenges that are unique to Alzheimer's clinical trials:

- The affects of the disease on memory, thinking, and decision making may make it difficult to comply with the clinical trial rules and protocols.
- Many people with Alzheimer's also have other serious medical conditions, such as heart disease, diabetes and cancer, that may (1) disqualify them for certain clinical studies, and (2) make it hard or impossible for them to continue in a study.⁴
- Older, less healthy study participants are more likely to die during the course of a study.
- Almost all Alzheimer's trials require the participation of a proxy and/or caregiver in addition to the person with Alzheimer's, essentially doubling the number of people in the study, making recruitment and retention more challenging.³



Why should I consider participating in an Alzheimer's disease clinical trial?

- Participants in clinical trials receive a high standard of care. All participants receive regular care related to the study and opportunities to talk to study staff. Research shows that people involved in studies tend to do somewhat better than people in a similar stage of their disease who are not enrolled, regardless of whether the experimental treatment works.
- Improved treatments can never become a reality without testing in human volunteers.
- These studies may have a measurable impact on current and future people with Alzheimer's.
- Every clinical study contributes valuable knowledge, whether or not the tested treatment works as hoped.²

What happens in an Alzheimer's disease clinical trial?

If people with Alzheimer's and/or family members are interested in participating in a clinical trial, they will be asked to sign an informed consent form to affirm that they understand the trial and are willing to participate. Next, there will be a screening for participation. Different trials have different inclusion and exclusion criteria, so being excluded from one trial does not mean exclusion from another. Generally, participants can be a part of only one trial or study at a time.³

Once enrolled in a clinical trial, a first (or "baseline") visit is scheduled, in which cognitive and/or physical tests may be administered. Participants in treatment trials are then randomly assigned to distinct treatment groups. Participants and family members will be asked to follow the trial protocol and report any issues or concerns to researchers, and they may visit the research site for periodic cognitive, physical, or other evaluations and for discussions with staff.³

Throughout the trial, investigators may collect information on effects of the intervention, disease progression, and the safety and well-being of the participant and caregiver. Participants should also continue to see their regular physicians for usual health care. At the end of the trial, investigators may or may not directly notify participants of the trial's findings.³

What should I think about before deciding to join an Alzheimer's clinical trial?

- Are the time commitment and location acceptable? Clinical studies can last for years and may require multiple visits to study sites, such as private research facilities, teaching hospitals, Alzheimer's research centers, or doctors' offices.
- What are my and my family's expectations about the results of trial, and whether or not the person with Alzheimer's will "get better"? Are these expectations realistic?
- Will I be willing to continue in the research study if the person with Alzheimer's is not "getting better"?
- What is my personal comfort level regarding whether the person with Alzheimer's is getting the experimental treatment or a placebo?
- What are the potential risks associated with the treatment (or other activities) in the trial.³

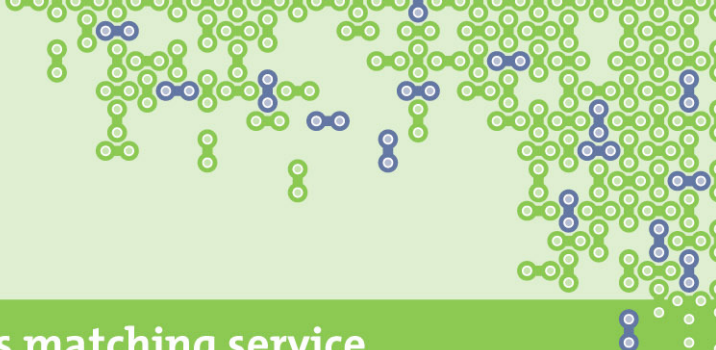
Important: Volunteers can withdraw from a research study at any time they or their physician feels it is in their best interest.³

How can I find out about Alzheimer's disease trials and studies?

There is ground-breaking research going on right now that could have a measurable impact on current and future people with Alzheimer's disease. Information about the latest Alzheimer's disease clinical trials and studies is available through a number of sources, including:

- Alzheimer's Association TrialMatch™ – a confidential and free, interactive tool created by the Alzheimer's Association that provides comprehensive clinical trial information and an individualized trial matching service for people with Alzheimer's disease and healthy volunteers. Alzheimer's Association TrialMatch can be accessed online at alz.org/trialmatch or by calling (800) 272-3900.
- Your doctor, who may know about local research studies that may be right for you.
- National Institute on Aging (NIA)-supported Alzheimer's Disease Centers or specialized memory or neurological clinics in your community that could also be conducting trials.

References



alzheimer's association clinical studies matching service

1. National Institutes of Health, National Institute on Aging, AD Clinical Trials: Questions & Answers. Accessed on April 8, 2010: <http://www.nia.nih.gov/Alzheimers/ResearchInformation/ClinicalTrials/trialsQandA.html>.
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3. National Institute on Aging. National Institutes of Health. U.S. Department of Health and Human Services. Participating in Alzheimer's Disease Clinical Trials and Studies. September 2009; 09-7484. Accessed on April 8, 2010: <http://www.nia.nih.gov/Alzheimers/Publications/trials-studies.htm>.
4. Alzheimer's Association. 2010 Alzheimer's Disease Facts and Figures. Alzheimer's & Dementia; vol. 6. Accessed on April 20, 2010: http://www.alz.org/documents_custom/report_alzfactsfigures2010.pdf.