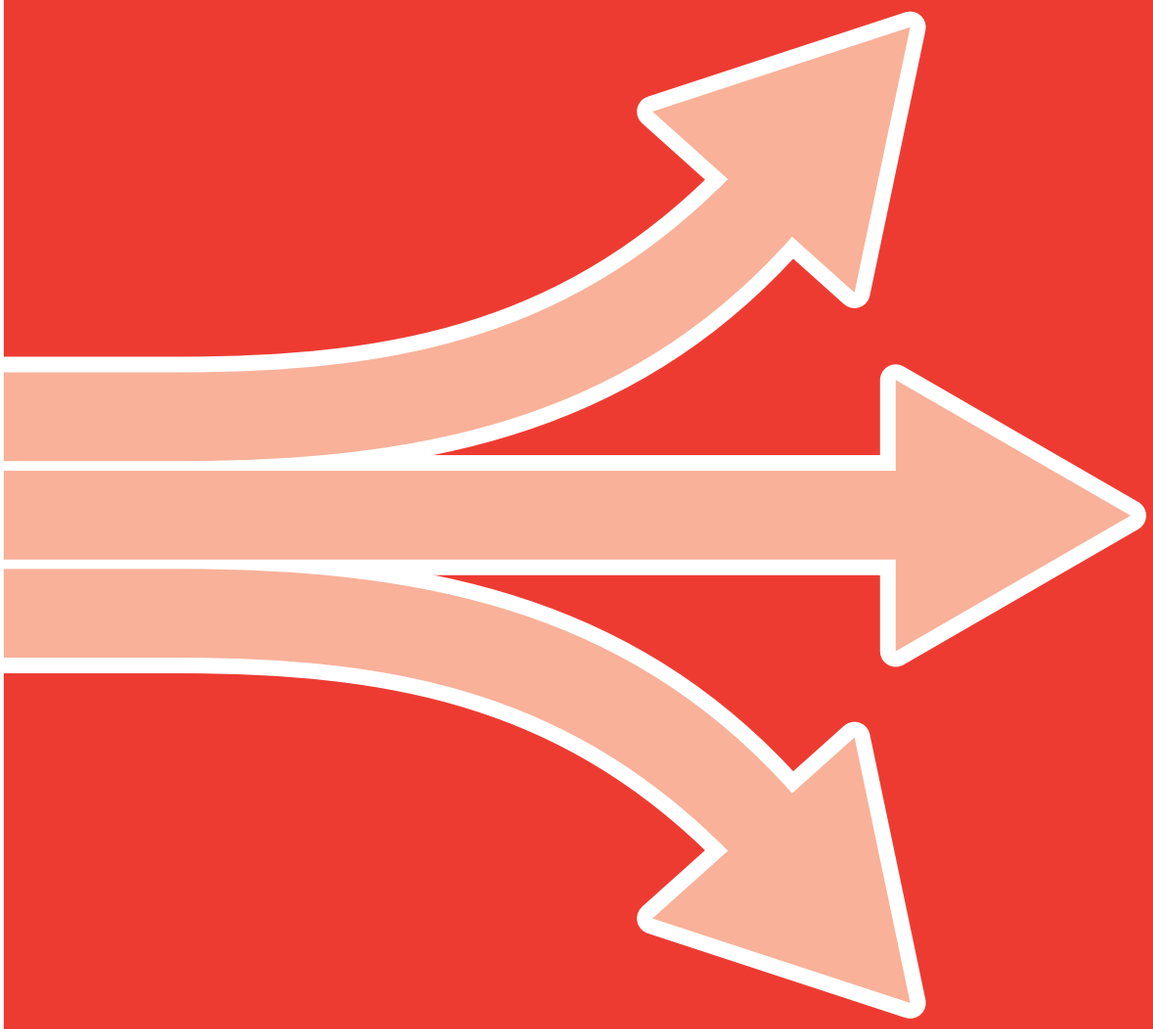
Alzheimer's Disease International

Your guide to getting involved in clinical trials



The development of new medicines depends on clinical trials …

… and **you** have a role!

Alzheimer's Disease International supports Alzheimer's disease clinical trials. We know that research is the engine that powers medical progress. Clinical trials give people with Alzheimer's disease a chance to help improve treatments for this disease.

The importance of clinical trials

Thanks to advances in our understanding of Alzheimer's disease, scientists are making great progress in finding new ways to help treat, and someday prevent, the disease. Before any new medicine is used to treat a disease, it must be carefully tested in clinical trials to make sure that it is safe and that it works in people.

To make sure that trials are conducted ethically, there are many rules and standards for how a trial proceeds, including:[1]

- The use of highly qualified researchers
- External and independent review by an institutional review board or an ethics committee
- Ongoing monitoring of all trial sites
- The use of informed consent documents that outline the risks and potential benefits of participation
- Ability for all volunteers to withdraw from the trial at any time

Clinical trials move medicine forward, helping researchers make advances in Alzheimer's disease treatment.

Without clinical trials, there can be no new treatments or cures.

Why should you participate in a clinical trial?

Without clinical trials, there can be no better treatments for Alzheimer's disease.

Volunteers are urgently needed to be part of medical research.[2]

By participating in a clinical trial, you can:[2]

- Help others, including future generations, who may be at risk for Alzheimer's disease
- Try potential treatments before they are widely available
- Play a more active role in your health care
- Be a part of efforts to develop new Alzheimer's disease medicines

While you are participating in a clinical trial, you will receive expert medical care at a leading hospital or other facility. Often, the experimental treatment and medical care relating to the clinical study are free of cost.[2] In addition, you will continue to receive your normal medical care from your primary physician.

Most volunteers would participate in a clinical trial again

Of 2261 research participants surveyed, 84% said they would join a clinical trial again.[3]

Harris Interactive, 2005

"My message to others would be, have an open mind to being a clinical trial subject. Learn all you can about the trial's purpose and requirements and go for it!"

Barbara Holtz, clinical trial participant
CISRP Patient Perspective[4]

How new medicines are developed

The importance of clinical trials

It can take an average of 13 years to develop a new medicine, from identifying a new compound to testing it in clinical trials, to making it available for your doctor to prescribe it.[5]

Clinical trials are conducted in phases. At each phase, researchers try to answer different questions about the experimental medicine they are researching. Progression from one phase to the next generally requires success in the prior phase.

Preclinical ▶ **Phase 1–3 trials** ▶ **Registration** ▶ **Phase 4 clinical trials**

An experimental medicine first goes through rigorous testing in the laboratory. If the experimental medicine has the potential to treat an illness, it can move on to clinical testing in people.[6]

Testing in people is done in three phases of clinical trials.

The goal of **Phase 1** is to test safety.

Phase 2 tests how well an experimental medicine will work to treat Alzheimer's disease.

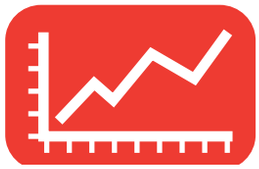
In **Phase 3** the experimental medicine is tested in large numbers of people to confirm how well it works. Phase 3 trials may compare the experimental medicine to another commonly used medicine for Alzheimer's disease treatment, such as a cholinesterase inhibitor.[6,7,8]

Results from all phases of the clinical trials are provided to the health regulatory authorities to evaluate the risks and benefits of the experimental medicine and determine whether to approve the medicine for broad use. If the regulatory authorities approve the new medicine, it can then be prescribed by physicians to their patients.[6]

Phase 4 trials are conducted after a treatment has already been approved. In Phase 4 trials, researchers collect additional valuable information, such as the long-term risks or other benefits of the medicine.[6,7]

The clinical trial process

AVERAGE LENGTH OF PROCESS 13 YEARS



Preclinical ▶ **Phases 1–3** ▶ **Registration** ▶ **Phase 4**

Rigorous laboratory and animal testing determines a compound's potential as a medicine

Efficacy and safety are examined in people, including those with the disease

Health regulatory authorities use trial results to decide whether to approve the medicine

Researchers collect additional information on an approved medicine (such as its long-term risks, benefits, and optimal use)

Phase 1 ▶ **Phase 2** ▶ **Phase 3**

Length of Phase	From 3 weeks to 3 months	From 6 months to 2 years	From 6 months to more than 2 years
Number of Participants	20 to 80 participants	100 to 300 participants	More than 1,000 participants
What the phase is testing	Is the experimental medicine safe?	Does the experimental medicine work in people with Alzheimer's disease?	Confirm in larger studies how well the experimental medicine works in people with Alzheimer's disease.

Potential concerns when considering participating in a clinical trial

Potential concern	Helpful information and who to talk to
There may be unpleasant or serious side effects related to the experimental treatment being studied.	The experimental medicine has already undergone rigorous testing to understand safety and reduce side effects. However, if you do experience unpleasant side effects, staff will be available to speak with you 24 hours a day, 7 days a week.
The experimental treatment may not be effective.	Though an experimental medicine may not work, every trial produces important knowledge about Alzheimer's disease. This may help to develop future treatments.
Some people with dementia may not be able to make decisions about participating in a clinical trial.	As with many decisions about Alzheimer's disease, sometimes these decisions are made by another person, such as a caregiver or family member.
Clinical trials can last years. Also, trial sites may require multiple visits on a specific schedule, and the testing center may not be close to where you live.	To help you decide whether to participate, it is important that you and your caregiver understand the trial requirements and how long the trial is expected to last. Be sure to express any concerns to the trial site staff. Many sites will be very supportive and will help you as appropriate. For example, they may provide help with transportation to and from the site and pay you for your time, travel, and lodging.
Participants are not allowed to know whether they are receiving the experimental medicine or a placebo (sugar pill) during the study.	A trial comparing an experimental medicine to a placebo is critical to better understand how well the experimental medicine works. In clinical trials, experimental treatments are often compared with placebo to assess the treatment's effectiveness, as well as its safety and tolerability. In most longer term clinical studies, you will be able to remain on your current Alzheimer's medication.
The patient may already be taking a medicine for Alzheimer's disease.	In most Alzheimer's disease trials, patients can continue with their current treatment.

It is important to speak with your physician or the clinical trial staff about these or any other concerns that you may have.

Questions you could ask

If you are interested in participating in a clinical trial, you probably have questions you would like to ask. Here are some suggestions to help guide you.

"The comfort I got from working with a team of people who were sympathetic, empathetic, and driven to help was enormous. They were like another family to me, and they put us at the cutting edge of research."

Brennen Teel, clinical trial participant [4]

Questions to ask your doctor

- If I am in a trial, will you continue to be my doctor and provide me with my regular care?
- How do we know which clinical trial is right for me?
- What do I do if I have any side effects?
- Will you review any laboratory results collected in the trial?

Questions to ask the clinical trial staff

- What has already been learned about the experimental medicine?
  - Why do researchers believe this experimental medicine may work for Alzheimer's disease?
  - What are the risks associated with this experimental medicine?
  - Are there any risks if this experimental medicine is taken at the same time as my other medications?
  - Can I continue with treatments for my other conditions that my regular doctor has prescribed for me?
- What tests will be given during the trial?
- What side effects might occur, and what do I do if I have any?
  - How do the possible side effects and benefits of this experimental medicine compare with the side effects and benefits of my current treatment?
- How often will I need to visit the clinical trial site?
- How long will the trial last? How much time will each visit take?
- Where and when will the testing occur?
- How will I know that the experimental medicine is working? Will I be informed of the results?
- Will some patients in the trial take a placebo? If so, what are the chances that I will take a placebo?
- Do I have to pay for any of the trial? Are my expenses reimbursed? Will I be paid to participate in the trial?
- How will you keep my doctor informed while I am participating in the trial?

What are the steps when participating in a clinical trial? [2]

After an initial telephone screening, you will be scheduled to visit the clinical trial facility to find out more about the trial. The clinical trial investigators will find out your medical history. In addition, they will determine whether you are eligible to participate in the trial. Then you (or your caregiver) will sign an informed consent form, which includes details about the trial, such as its purpose and how long it will last. This document will also explain required procedures, as well as the risks and potential benefits of the experimental medicine you will be taking. Please see below for more information on informed consent.

If you are eligible for the clinical trial, a first visit is scheduled for cognitive and/or physical tests. You and your family members will receive information on the clinical trial, including contact information where you can report any issues or concerns. Clinical trial staff are available 24 hours a day, 7 days a week to help you if you have any questions or are experiencing any side effects with the medication.

You may be asked to visit the research site for additional cognitive, physical, or other evaluations and for discussions with staff. Investigators collect information on effects of the experimental medicine, disease progression, and the safety and well-being of you and your caregiver. You will continue to see your primary physician for standard health care.

What is informed consent?

Informed consent gives you important information about the trial before you decide whether to volunteer. Informed consent tells you about your rights as a trial participant as well as the details about the trial. Informed consent is a medical and legal requirement and provides you with helpful information, including:[1]

- Why the research is being done
- What researchers want to accomplish
- What will be done during the study and for how long
- What risks are involved
- What, if any, benefits can be expected

For those with limited mental capacity, having a family member or caregiver can be helpful with informed consent. You may leave a trial at any time, even if you have already agreed to participate or have begun the trial.

Clinical trials set high ethical standards

Before any clinical trial begins, an ethics committee must approve all procedures. These committees make sure the following important issues are true:[1]

- The research must advance health or knowledge
- The trial must meet high scientific standards
- The participants selected for participation meet the criteria for the scientific purpose of the trial
- The potential benefits and knowledge gained for society must outweigh the risks
- Unbiased investigators must review the research
- Participants should be informed about the research and provide their voluntary consent
- Trial participants should have their privacy protected, the opportunity to withdraw, and their well-being monitored

Be a part of the future of Alzheimer's disease treatment!

Ask your doctor about clinical trials currently recruiting participants or contact your local Alzheimer's disease association for more information

For more information

Alzheimer's Disease International provides general information on Alzheimer's disease at www.alz.co.uk. Please contact your national Alzheimer's association or visit the following websites:

- List of national Alzheimer's associations: www.alz.co.uk/associations
- EU Clinical Trials Register: www.clinicaltrialsregister.eu
- Listing of trials being conducted in the United States and around the world: ClinicalTrials.gov
- The US-based Alzheimer's Association: www.alz.org

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Alzheimer's Disease International

Alzheimer's Disease International: The International Federation of Alzheimer's Disease and Related Disorders Societies, Inc. is incorporated in Illinois, USA, and is a 501(c)(3) not-for-profit organization

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