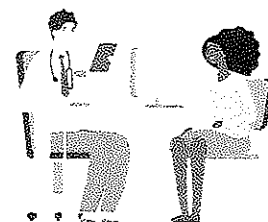


# Clinical Research and Alzheimer's Disease

## What is a Clinical Trial?

Clinical trials are research studies performed in people that are aimed at evaluating a medical, surgical, or behavioral intervention. They are the primary way to understand if a new treatment, such as an investigative treatment, diet, or medical device (such as a pacemaker) is safe and effective in people. A clinical trial may learn if a new treatment is more effective and/or has less side effects than the standard or current treatment(s).



## Clinical Trials Are Conducted in Phases:

### Phase I: Is the investigative treatment safe?



In this first phase, the **safety and dosage** of the investigative treatment is tested among 20-100 healthy participants. This phase lasts several months and looks at what the drug does along with what the body does to the drug. The research team closely monitors participants for side effects. Phase I trials also look at how the body responds to different doses of the investigational treatment. This phase occurs over the course of several months.

### Phase II: Does the investigative treatment work?



Phase II clinical trials typically include 25-100 participants with the disease being studied. Over the course of several months up to two years, researchers are looking to see if the investigative treatment works at **treating the disease or improving quality of life** for someone with the disease.

### Phase III: Is it better than what's already available?



Phase III trials compare the **safety and efficacy** of the investigative treatment to the current standard of treatment. These trials typically take 1 to 4 years and includes hundreds to thousands of participants with the disease being researched.

### *Submission for regulatory agency approval, such as the FDA*



### Phase IV: What else do we need to know?

After the drug has been approved, researchers watch the treatment over a long period of time to assess how well the drug is working and wide side effects may show up after a longer period of time.

## ASPECT™ is a phase III clinical research study for agitation associated with Alzheimer's dementia

### Symptoms of Agitation

- Restlessness
- Shouting/screaming
- Hitting self or others
- Pacing/aimless wandering

### ASPECT™ Study Eligibility:

- Be between the ages of 50 and 90
- Have a diagnoses of probable Alzheimer's dementia
- Have moderate-to-severe agitation that interferes with their daily life
- Have a reliable caregiver who spends a minimum of 2 hours per day, 4 days per week with them and is willing and able to comply with all study procedures



If you or a loved one is suffering from agitation, you may be eligible to participate in the ASPECT™ study. Visit [AgitationInAlzheimersDisease.com](http://AgitationInAlzheimersDisease.com) or scan the QR code to learn more.



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