



There are currently 5 million Americans affected by Alzheimer's disease and that number is increasing at an alarming rate. However, there is great optimism and excitement among Alzheimer's disease researchers and clinicians for the arrival of the next generation of treatments for this life-robbing disease. These new drugs are likely to do something that no treatment to this point has done—slow the progression of the disease. For these drugs to become available, they must be evaluated through clinical trials. As you read in the fall 2007 *Alzheimer's California Southland Quarterly*, many people are enthusiastic to participate in these trials, but more are needed. People like Louise Trevino and Alice Wennerholm understand that not only do they have everything to gain by participating, but that only through clinical trials research can the drugs that were yesterday's experimental therapies become tomorrow's standard for care.

Clinical trials are research studies involving volunteers and

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**making a difference  
the importance of participating**

they represent the final stage in the drug development process. Clinical trials have several basic parts. To be included, one must meet specific requirements depending on the trial. The requirements might be based on age, disease severity, or the previous use of certain medications. Importantly, many patients assume that taking a drug such as Aricept might prevent them from participating in a clinical trial and this is often not the case.

In clinical trials investigating a new drug, some of the participants typically receive the drug under investigation while some receive a *placebo*, or sugar pill. This sugar pill provides a standard for comparison to see if the new drug is effective. Neither the person participating in the study nor the physician knows whether the active drug or the placebo is given. This is referred to as *blinding*. Blinding is necessary to ensure that the study is performed without bias.

At the conclusion of the study, the results are compared to see how the new drug differed from the placebo. After comparison of the groups, the participants who were receiving the active drug as part of the study are often asked to continue taking the drug and the participants who were receiving the placebo

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are often switched to the active drug. This is done in order to provide more safety data. Because all participants in these studies know that they are receiving the active drug, this is called an open-label study and represents a mechanism by which even those assigned to the placebo group in a clinical trial may end up receiving the active drug. If the drug is safe and effective, it may become available to all patients who would benefit from it.

It will be important for people involved in clinical trials for new drugs for Alzheimer's disease to remember that, because of the nature of these drugs, the effects of new agents may be subtle. These drugs are intended to prevent the disease from becoming worse. Participants may not notice substantial differences in

cognition as a result of therapy. For this and many other reasons, it is crucial that people enrolled in trials try to complete the course of trial medication, even if they are unsure whether it is affecting their symptoms. Nevertheless, people in any clinical trial are free to stop participation at any time.

There are many reasons to participate in a clinical trial. It is an opportunity to make a substantial contribution to cutting-edge advances in medicine and science. Through participation, people are helping thousands of others. There are also several benefits of participation. For example, participants have the opportunity to see physicians at the nation's finest medical institutions often free of charge. Participants may also receive therapy that is not otherwise available, again free of charge. This is especially pertinent in Alzheimer's disease, since only these new therapies are likely to alter the course of the disease. For some studies, people also receive compensation for their time and participation.

Research institutions like our own are committed to stopping Alzheimer's disease but we cannot do it without your help. Only with the participation of people in clinical trials can we learn how to fight and defeat this terrible disease. You have the power to contribute to the exciting advances in Alzheimer's disease research and together we can make a difference.

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