

**Clinical Drug Studies**  
**Bee Pollock, B.S**  
**Dept. of Psychiatry and Neurology**  
**Tulane University School of Medicine**

Q: What are clinical trials?

A: Clinical Trials are the way all new drugs are brought to your drugstore shelf.

They are divided into 4 phases, 1,2,3, and 4.

Phase One is a very small, very basic testing of the compound or device on a small, like 10-20 NORMAL volunteers to determine if there are any really obvious bad side effects. Assume all goes well. Phase I may continue, or it may move into Phase 2.

Phase Two trials are again, very small numbers of people, but this time, with the indication for the disease for which the drug is aimed. This may involve 100 persons. Also, at this time, DOSE FINDING studies are being done. This is to find the best dose for treating the disease and not causing bad side effects. Phase 2 may involve up to 1000 or be as small as a group of 200. Phase Three is the testing of the drug in people with the disease. Many sites are usually involved in an effort to get people of all races and ethnicity involved. We now that males and females react differently to the same drug. We also know that different ethnic groups react differently. And finally, Phase Four. This is after FDA approval.

Q: Who is eligible?

A: Eligibility is determined by the inclusion and exclusion criteria/requirements for each clinical trial. These are very specific and target the disease population. If the study is pediatric, the age limits reflect this. Likewise, in Alzheimer's Disease (AD) trials, the age limits reflect the targeted group: those who are at least 45 and

older. Some studies will have an upper age limit while others don't. Generally, you have to be in pretty good health to participate in a clinical trial. They want to have the answers nice and clear. If someone had a history of really severe coronary artery disease with multiple heart attacks, stroke, etc. they might be excluded. If they were on a trial and had a fatal heart attack, it wouldn't be clear what caused the incident, their underlying condition or the Study Drug.

Q: How do I get my loved one enrolled?

A: All Clinical Trials have several contact numbers, but you have to find them! If a trial is advertised locally, the site named and/or the physician's name and phone number will be included. Likewise if it's a national ad, they might have a 1/800 number.

Q: What are the benefits of clinical trials?

A: The first benefit of participating in a clinical trial is the knowledge gained about the drug and disease through participation. Without the wonderful volunteers who are study participants there would be no new drugs. Each person is making such a valuable contribution to others with the same condition to that the body of knowledge will be increased. Thus, they and others may benefit.

Some trials offer cash. The FDA is very careful about this, the amount cannot be too much – don't want to influence people to participate just for the money. Their big reason is the chance to get a new drug several years before it is commercially available. Many studies have open-label (everyone gets the study drug).

Q: What trials do you have currently at Tulane?

A: We have a variety of AD trials and a mild cognitive impairment trial also. Two of the trials involve 2 brand new drugs that we think show great promise. Both can be taken along with Aricept and Namenda. In fact, Aricept 10mg/qd for 3 months prior to study entry is an inclusion requirement for one study. We are also doing an Aricept + Lipitor study in mild to moderate AD. The person cannot be on a statin drug currently, nor require treatment with one. Living in New Orleans with all our good food, this is also a very important trial. We've all read how the use of statins helps with heart problems. This study hopes to show that the use of statins will help prevent/slow the progress of AD.

Q: What do I have to do as a caregiver if my loved one is enrolled in clinical trials?

A: The Caregiver (CG) role is defined in each protocol. Basically, the CG assures the safety of the medication – keeps it safe from others and makes certain that the drug is only taken, and taken correctly, by the person for whom it is prescribed. They act as a valuable source of information about the subject's progress. They must come with the subject to each and every clinic visit. The CG may or may not be the legal guardian. This is an essential role!

Q: Is there anyone else doing clinical trials in New Orleans?

A: There are numerous clinical trials sites. I see ads in the paper but I don't know who they are. Despite what I said about ads having the physician's name, many of the local ads don't. Some only have an 800-number and not even list a location. I do know that LSU does clinical trials. It also depends on the disease being studied.

Q: How can people get in touch with you for information on Tulane's clinical trials?

A: The contact information for the Department of Psychiatry and Neurology Clinical Trials is 1/800-588-5800, then press \*. This number is not answered nights or on weekends. Office numbers are: for Bee Pollack, 988-7363, for Pam Rockmore, Study Coordinator, 988-1946, or for Yolanda Steptore 988-1758.

Q: Are there any drawbacks to participating in clinical trials?

A: Not really. You may not be able to take certain drugs because the protocol doesn't allow them. This is for your own benefit. For example, for the 2 days prior to the extensive memory testing that we do for the studies, many protocols outlaw certain drugs. They may impair your thinking. Think about how groggy you feel if you've taken Benadryl.

Q: Thanks, Bee. You've been great for doing this!

A: You're welcome.