

What Is Clinical Research?

by Madeleine DuPree, M.D.

The radio and newspapers resound with multiple advertisements for clinical research studies. Yet, how much do you really know and understand about research and if you should participate? The following few paragraphs will provide background information on clinical research and enable you to make that decision.

Prior to human testing, a drug company will usually conduct extensive experiments on the product (usually drugs) on animal models. Once sufficient and successful data is accumulated, the pharmaceutical company will submit the results to the FDA (Food and Drug Administration) for approval. Human testing begins after FDA approval and is called a **PHASE I** study. This study or trial is mainly concerned with the drug's **safety** i.e., how the drug affects the body during **absorption** (how it gets into the body), **metabolism** (how it changed within the body) and **excretion** (how it is eliminated from the body). Only a small number (20-100) of **healthy** subjects will be observed for side effects at different dosages, usually over a few months. About two-thirds or more of the trial drugs pass this phase.

The **Phase II** study will focus on how well the drug works or its **efficacy**. Several hundred people will be selected to participate for up to two years. During this phase, most trials have two arms or groups i.e., one is the drug to be tested and the other is the control who receive standard treatment or a placebo (an inactive substance which is used as a basis for comparison with the results of the study drug). These studies are usually blinded (subjects and/or clinical staff do not know who obtains the trial drug). Only one third of the drugs tested reach Phase III.

Over several years, hundreds to thousands of subjects will enter **PHASE III** trials. The large numbers are needed to further test the **effectiveness, benefits and side effects** of the study drug. Seventy to ninety percent of the drugs that enter Phase III will be successfully completed and submitted to the FDA for approval for marketing.

After marketing (FDA approval of the drug), there may be later testing. These **LATE PHASE III/PHASE IV** studies will concentrate on **long term effectiveness** and influence on the patient's **quality of life, comparative studies** with other drugs on the market and the drug's **cost-effective-**

ness in relation to other available drugs.

Who pays for these drug trials? Both private pharmaceutical/biotech companies and the government such as the National Institutes for Health are the **Sponsors** of the trials. Many times, they will contract intermediate organizations who will organize and monitor the studies called **CROs** and they will interact with the MDs and clinical staff who will conduct the trial. Frequently, the medical care is provided for and the participants may be paid a small fee for their time.

Research is voluntary so why should you participate in clinical trials? Many times, the medical care is comprehensive and provided for during the clinical trials. Also, the volunteers can gain access to promising drugs or treatments before they become available on the market. Many enter clinical trials because they want to be on the cutting-edge of medicine while some simply want to help others and the advancement of medicine. Whatever the reasons, it is important to make an informed choice. For common questions asked about research and more detailed information, please go to www.centerwatch.com.

South Florida Gastroenterology Associates (SFGA), a premier physician provider of digestive disease disorders in Palm Beach County, organized **Consultants for Clinical Research of South Florida (CCRSF)** in 2002 so that their patients would have access to new and innovative medical care provided by the latest clinical trials.

CCRSF conducts clinical trials in a caring environment, supported by the most dedicated physicians, nurses and staff. I am a board-certified Internist and Fellow of the American College of Physicians. I bring twelve years of primary care in South Florida to CCRSF. For the past two years, our research has included Irritable Bowel Syndrome (IBS), Functional Dyspepsia (FD) Barrett's Esophagus and Erosive Esophagitis, Inflammatory Bowel Disease (IBD), Gastroesophageal Reflux Disease (GERD), and Constipation and Functional Diarrhea. We encourage you to call us if you have any questions about clinical research or this article.

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Scientist Claims Magic Bullet For Headaches

An electronic gun which is said to kill off headaches has been developed by scientists.

The extraordinary alternative to pain relief pills works by firing magnetic impulses into the brain.

Such therapy could be particularly beneficial for migraine sufferers, for whom conventional treatments such as paracetamol often prove ineffective.

It is claimed to block the strongest headaches and possibly even avert epileptic fits by soothing the brain cells from which they originate.

The gun was developed by Adrian Upton, head of Neurology at McMaster University hospital in Ontario, Canada. His work, to be published in the Neurology journal, suggests migraines are caused by waves of elec-

trical energy spreading over the cortex, the outer layer of the brain.

Tests have shown that after each neuron—a nerve-impulse-conducting cell—emits a signal to its neighbors, it briefly calms down.

Dr. Upton's theory is that hitting these cells with a magnetic pulse could stop subsequent signals, blocking the headache before it gathers momentum.

So far, research has been carried out with laboratory apparatus, but Dr. Upton has shrunk this into a handheld device that he plans to market to the public.

The headache gun, which runs on six AA batteries, could be on sale in the US within two years.

(Andy Dolan, Courier-Mail. Aug. 4, 2004)

Cranberry Tops Red Wine With One-Two Punch

New findings reveal that the popular berry, the cranberry, boosts good cholesterol and shields the heart with its unique antioxidant muscle.

For years, red wine and grape juice have been touted as the drinks that provide heart healthy benefits. Now scientists are discovering that cranberry juice may be equally good for the heart. Light cranberry juice cocktail packs a knockout one-two punch, with both "anti-stick" and "antioxidant" bang. This adds to the long-standing research that connects cran-

berry juice with helping ward off urinary tract infections.

Conducted at Canada's Laval University, the study found that the cranberry improves circulation by increasing the level of good cholesterol and acting as a powerful antioxidant. Additionally, a recent laboratory study at the William Harvey Research Institute in England found that a serving of cranberry juice each day could be as good for the heart as red wine—without the drawback of alcohol.

—NAPS

The Variable Annuity Mess: Who's Responsible?

The standard line is that variable annuities (VA's) are not bought; they are only "sold." The nature of the product is that of a "wrapper" with associated fees with mutual funds that generally can be bought without the expensive wrapper and "surrender charges." As far as the insurance portion which provides a mortality benefit, this also can be purchased outside of the annuity for considerably less.

Why would a financial advisor or planner recommend a variable annuity to a client? Well, as John Dillinger said, "that's where the money is." Variable annuity products generally offer the broker the highest fee of any products he can sell.

There are some situations where the tax-deferred growth offered by variable annuities makes sense. When a high income earner in his/her 50's needs tax deferred growth and does not require liquidity for the surrender period, the variable annuity may make sense. However, the explosive growth of variable annuities from 23 billion in 1990 to almost 850 billion in the year 2000, and the prevalence of "bonus annuities" and 1035 exchanges indicates that the growth is fueled by the "need to fill a sale" as opposed to a "sales to fill a need."

The securities industry has suitability conduct rules which require "reasonable grounds" to believe the transaction is suitable in light of the

customer's financial needs. The information to be obtained by the representative includes the following:

1. The customer's existing insurance coverage
2. The customer's ability to understand the complexity of variable annuity products
3. The customer's need for liquidity
4. The customer's need for retirement income
5. The customer's risk tolerance



Howard M. Rosenfield

Although industry rules also require that the broker (a/k/a registered representative or financial consultant) have a "thorough knowledge of the specifications of each VA recommended," the complexity of these products requires a sophistication most reps do not have.

It is up to supervision of the brokerage firms to design and enforce supervisory systems that ensure that VA's continue to help achieve investment objectives and not merely a broker's sales targets. Failure of brokerage firms to enforce these rules will lead to the imposition of liability, regulatory sanctions, and product failure.

Howard M. Rosenfield is an attorney specializing in arbitration and mediation for investors who have a dispute with their broker and/or brokerage firm. He is a member of the Public Investors Arbitration Bar Association (PIABA) and can be contacted by calling 1-800-637-3243.

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