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SOUTHEASTERN Research GROUP

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Inside This Issue

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Message from the Director

In general, clinical trials are used to test the safety and effectiveness of drugs and medical procedures in human beings. This ongoing collaboration between physician-researchers and study volunteers is one of the foundations of modern healthcare, because clinical trials help set the standards for patient care. There are potential benefits, as well, for clinical trial volunteers. For instance, volunteers with existing diseases or conditions can play a more active role in their own healthcare, gain access to new research treatments before they are widely available, and help others by contributing to medical research. An estimated 1 million Americans each year are willing to put the potential rewards from enrolling in a clinical trial ahead of the possible risks. They deserve our gratitude and support.

The lead story in this first edition of the Southeastern Research Group Newsletter is reprinted from the Boston Globe. Appropriately for our inaugural newsletter, it is one person's first hand account of their participation in a clinical trial in their own words. It points out the difficulty and the potential of the current system for bringing new medicines and treatments to the people who stand to benefit from them.

Ronald Norton
Director of Research

Giving the sick a chance for help, hope

By Jerry Fensterman | August 3, 2006 Boston Globe

I AM BATTLING an incurable cancer. I'm alive, thanks to a clinical trial drug. News of cancer breakthroughs captures my attention nearly daily as new drugs -- and redeployed old ones -- slow, stop, reverse, and even cure previously fatal cancers. Will a miracle come in time for me or for those like me?

Since only 5 percent of cancer patients participate in clinical trials, it takes three to five years to gauge a new therapy's effectiveness. According to a former director of the National Cancer Institute, this could be shortened to just one if 10 percent of patients would participate in clinical trials.

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Doubling participants should be easy.

A Harris Interactive survey of 6,000 cancer patients conducted in 2000 reported that 85 percent of the respondents ``were unaware that participating in a clinical trial was a treatment option.'' That seems to be why only 5 percent of patients participate in clinical trials. Attracting another 5 percent should be a breeze, especially since all parties want better drugs faster. Why is there a problem? My experience may reveal some answers.

When my cancer became incurable, my only hope lay in clinical trials. I expected to find a well-organized system to help me learn about and enroll in appropriate trials. This is hardly what I found. I learned of good trials not because of an organized and equitable system but because my oncologist is a leader in kidney cancer. I'd only leaped the first hurdle.

I planned to call trial doctors in my hometown of Boston, Chicago, and New York to see if their trials were right for me. But to be taken seriously, I was told, I would have to visit. Doctors are busy, and phone calls don't demonstrate sincere commitment. I told myself I'd go anywhere to save my life. But my one trip to Chicago demonstrated just how hard it would be to fly there twice per week and continue those trips indefinitely if the drug worked.

Expenses mount fast. Travel is costly. My employer paid my salary despite time missed. How many other people would be so fortunate?

There may also be variable costs to participate. Two of my trials required only co-pay. One, however, amassed bills of $7,000 in less than two months. Such costs are a hardship in any circumstances, but more so now since I have gone onto long-term disability and my income is down 60 percent.

Most trial drugs are free. Mine was until it received Food and Drug Administration approval. Because I'm well insured, I only pay 1 percent of the $4,300 monthly bill. Imagine the person who successfully navigates the trial system but lacks health insurance.

I'm lucky. I live close to major research centers. My doctor leads many trials and knows of others. My employer was unusually supportive. I possess sufficient moxie to advocate for myself. And I do have that insurance. Missing even one of these characteristics might doom my chances.

Improving the system won't be easy. Human experimentation demands extraordinary caution, well-organized administration, and oversight. Achieving cost efficiencies is easier in larger systems. Yet we have to do more to help the many people who don't share my advantages.

Given the vast profits of the pharmaceutical companies and the public good at stake, it doesn't seem too much to ask all interested parties to partner in improving this system, making it easier for sick or dying patients to participate in clinical trials without regard to where they live or how much money they have. That includes not having to pay one penny for the right to be a guinea pig. After all, you may one day live a better life because of the vomiting I did -- certainly on my behalf but possibly also on yours.

Powerful national and global interests are served by making better drugs faster. More private and public funding would make a big difference. So, too, would demystifying and improving the clinical trial system. It seems an important and solvable challenge. Drug discovery is supposed to be the hard part, right?

Jerry Fensterman was the director of development for Fenway Community Health until he was disabled by kidney cancer. ■

Andrew Kelahan, former vice president of the Coalition of National Cancer Cooperative Groups, "if we don't do the clinical trials, we can't develop new treatments."

Considering a Clinical Trial?

If you or a loved one is considering a clinical trial you should be willing and able to become thoroughly informed about the process. Here are a few questions you'll want to ask.

- What is the purpose of the clinical trial? (In most cases a trial doesn't result in a cure.)
- Is the trial you are considering best for your situation?
- What advantages, if any, might the experimental treatment offer over existing treatments? What are the risks?
- What happens if you enroll in the trial and later decide you want out?
- Is the experimental treatment being compared with a standard treatment or a placebo?
- What if something goes wrong because of the trial and you need medical care? Who pays?
- Can you stay on the treatment after the study is over? If so who pays?

"While there are many safeguards in clinical trials, there is no substitute for an educated participant."

David Lepay, Senior Adviser for Clinical Science at the FDA

Why would I be interested in a Clinical Trial?

The patients in a clinical trial are among the first to receive new research treatments before they are widely available. How a treatment will work for a patient in a trial can't be known ahead of time. Even standard treatments, although effective in many patients, do not carry sure benefits for everyone. But, patients should choose if they want to take part in a study or not only after they understand both the possible risks and benefits.

The patients who take part in clinical trial procedures that do prove to be better treatments have the first chance to benefit from them. All patients in clinical trials are carefully monitored during a trial and followed up afterwards. They become part of a network of clinical trials carried out around the country. In this network, doctors and researchers pool their ideas and experience to design and monitor clinical studies. They share their knowledge from many specialties about cancer treatment and care. Patients in these studies receive the benefit of their expertise.

Based on what researchers learn from laboratory studies, and sometimes earlier clinical studies and standard treatments as well, they design a trial to see if a new treatment will improve on current treatments. The hope is that it will. Often researchers use standard treatments as the building blocks to try to design better treatments.

Southeastern Research Group Values

- Patient safety, comfort, and satisfaction
- High quality services and product
- Eager assistance of coworkers
- Fiscal responsibility
- Continuous education and improvement of skills and knowledge

Trials Currently Enrolling

Southeastern Research Group has studies currently enrolling for the treatment of:

- Hypogonadism/Low Testosterone
- Type II Diabetes
- Benign Prostate Hyperplasia
- Prostate Cancer
- Overactive Bladder

For more information on these or other trials please contact:

Southeastern Research Group, Inc. at (850) 201-0411