

Patients Helping Doctors (PHD) Program: How Can We Improve Recruitment and Retention in Clinical Trials?

Patients are the key to the search for new medical solutions for our most deadly and debilitating diseases. Whether by providing tissue samples, blood, and medical histories or by enrolling in clinical trials to test potential new therapies, patients can provide critical information and resources to the research process. Within each patient lies the key to a cure, yet a very low percentage of patients are actively engaged in supporting the research process.

Our Patients Helping Doctors (PHD) program initiative underlines the critical role patients can play in the search for cures and to give them the information they need to get involved. Presently, it can take more than 15 years for a new drug or therapy to pass through the basic research, development, and clinical trials that are necessary for it to receive Food and Drug Administration (FDA) approval and to become available to treat disease.

Human clinical trials — the only way of evaluating whether new drugs, experimental medical devices and surgical techniques actually work — are critical to medical progress. However, researchers are experiencing mounting difficulties finding volunteers for clinical trials: a problem expected to get worse as an increasing number of biotechnology products advance through the pipeline.

In order to accelerate the path to FDA approval, more streamlined ways of recruiting patients to studies are needed, while ensuring that the quality of clinical research is not compromised in the process. To achieve both these ends, barriers to trial recruitment and retention need to be identified and overcome. This challenge is a key objective of FasterCures.

Barriers to Recruitment and Retention of Patients for Clinical Trials.

Despite the fact that 63% of Americans say they would likely join a clinical research study, only 15% of those polled indicated they had ever participated in one, according to a study conducted by Research!America.

There are many reasons for the lack of involvement, including:

- **Patients do not have enough information about clinical research.** There is currently no national listing of all clinical trials taking place. Finding out about a specific clinical trial may be a haphazard process, dependent on a patient's doctor, location, and access to informational resources rather than on appropriateness/eligibility criteria. Less than 1 percent of relevant patients currently participate in clinical trials, but if participation could be increased to 15 percent, experts say more breakthroughs could be made.

- **Physicians aren't informing their patients about the possibility of enrolling in a clinical trial.** A recent poll conducted by Research!America indicates that only 6% of patients say their doctors have ever suggested they participate in a clinical trial. Another study by the Coalition of Cancer Cooperative Groups revealed that when informed about a clinical trial by their doctor, 40% of cancer patients either enrolled or tried to enroll. Ensuring that physicians are getting the word out on clinical trials is probably the most effective way to increase patient participation.

Physicians are often unaware that clinical trials are available and appropriate for their patients, or they choose not to participate in or refer their eligible patients to clinical trials. Primary care physicians often leave the discussion of clinical research to the patient's specialist. Moreover, even specialists outside of the academic setting may not be aware of trials.

- **Patients and doctors have misconceptions about clinical trials.** There is considerable mistrust in the clinical research process, because patients are unclear about how their information obtained during the clinical study will be used, and due to past abuses of racial and ethnic minorities in trials.

Physicians also have misconceptions about clinical trials. This may be because they believe that standard therapy is best, they fear losing control of the patient's care, or because referring to or participating in a trial is an administrative or financial burden on their practice. Some community physicians also indicate a mistrust of the academic or research centers conducting the trials.

What is FasterCures doing?

In September 2006, FasterCures brought together leaders in the clinical trials field to focus on what is fixable in the system, to highlight the work of innovators who are yielding results, and to look at the components of their successful strategies that go beyond the traditional approaches.

The report from that meeting — "Clinical Trials Recruitment and Retention: Best Practices and Promising Approaches" — is available at http://www.fastercures.org/pdf/FC_ClinicalTrials_report_art_spg.pdf.

FasterCures is looking for ways to work together with other organizations toward the kinds of real solutions identified at this conference, including:

- Creating a national registry of individuals willing to participate in clinical trials;
- Orchestrating a communications effort to highlight the critical role patients play in the search for cures and to give them the information they need to get involved;
- Partnering with community physicians to educate them about clinical trials, develop new incentives for their participation, and create "mini-clinical research organizations" to ease their administrative burden;
- Institutionalizing methods for making research protocols more patient-centered, such as revamping the informed consent process.

FasterCures is also making our Patients Helping Doctors Web site (www.patientshelpingdoctors.org) a resource for patients and professionals committed to reinventing clinical trials.

What can you do to get involved in Clinical Trials?

- **Talk to your doctor.** If you are diagnosed with a disease or condition,, talk with you physician about possible ways that you can participate in a clinical trial.
- **Contact patient advocacy groups.** Many patient advocacy groups have extensive information on clinical trials for specific diseases or conduct their own clinical research.
- **Become informed.** People without medical conditions can also participate in clinical trials. Patients and physicians can find for more information on clinical trials at our site www.patientshelpingdoctors.org.

FasterCures/The Center for Accelerating Medical Solutions is a nonprofit "action tank" formed under the auspices of the Milken Institute with a mission to identify and implement global solutions to accelerate the process of discovery and clinical development of new therapies for the treatment of deadly and debilitating diseases. FasterCures' webpage is www.fastercures.org