

THE PARTICIPANT

THE PATIENTS' PERSPECTIVE

Personalized search helps patients in need

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Finding an appropriate clinical trial can pose problems for many potential volunteers. Many patients lack the computer savvy needed to search for trials. When patients do reach a registry site that lists clinical trials, the listings typically use scientific or complex terms that can be hard to understand.

Add the fact that people struggling with a disease are often stressed and anxious, which makes it even harder for them to think clearly enough to decide whether a particular clinical trial is right for them.

When they do find a trial, many potential volunteers don't know the key questions to gain the information they'd need to make an informed decision about the trial.

To overcome these stumbling blocks, CISCRP launched its Search Clinical Trials expanded service earlier this year. (www.SearchClinicalTrials.org).

As part of this service, CISCRP staff members help patients find appropriate clinical trials. Volunteers can phone or send an e-mail to request a personal search when searching on their own seems difficult.

Some of the requests are anguished and heart-wrenching. They illustrate the emotional state of the volunteers and their need to find a clinical trial.

One person wrote in his e-mail subject line: "Desperate for Treatment." He was struggling with terrible pain from a torn meniscus cartilage and was looking for a test treatment that might help him.

Another e-mail came from a husband whose wife had stage IV breast cancer that had spread to her brain and lung. She was given about two months to live. He was hoping that getting into a trial immediately could help prolong his wife's life.

Still another person wrote in for his grandfather who had stage IV adenocarcinoma spreading throughout his stomach to his other organs, and was looking for any kind of experimental treatment.

Volunteers get help in finding trials

Response has been enthusiastic. "We've handled hundreds of requests since the program launched in January 2009," says Meaghan Dunn, Manager of Outreach & Customer Service at CISCRP.

"Many of the people who contact us don't know how to conduct an effective search over the internet or don't have much access to a computer. Our service is really helpful for them. They find it more useful to communicate directly with someone who can do the searching."

CISCRP staff members review each request, and within a day or two will conduct a search and send the requestor a packet of information listing trials available to them.

"I try to make each communication individual by including a personal note," says Dunn. "Users don't feel that they are simply receiving a print-out of a computer-generated list."

The CISCRP staff tries hard to find an appropriate trial, although it's not always possible. "It depends how rare their disease is, where they live, and how much they're willing to travel," says Dunn. All volunteers who contact CISCRP receive an educational brochure.

CISCRP is not involved in recruiting patients for clinical trials and is not involved in conducting trials. CISCRP neither recommends nor endorses any of the trials it finds through the Search Clinical Trials service. The organization's goal is to connect prospective clinical trials volunteers with the professionals who run the trials so the public can ask questions about their specific trial and their eligibility for a specific trial.

Pharmacists: Front line allies for clinical trials education

CISCRP is aiming to join forces with pharmacists as a way to help educate thousands of patients about clinical trials.

With over 56,000 pharmacies in America (according to the National Association of Chain Drug Stores), working with pharmacists to help educate the public could have a major impact on patient interest in clinical trials.

Pharmacists already discuss drugs, treatments, and side effects with patients. Talking about clinical trials is a logical extension of their daily interactions with the public. Right now, pharmacists are an untapped resource for community outreach.

CISCRP is hoping to change that by engaging pharmacists in educating the public about clinical trials.

Pharmacists are well-respected by the public and considered highly credible sources of information about drugs. According to Edith Rosato, RPh, newly-elected President of the National Association of Chain Drug Stores Foundation, pharmacists have been the most trusted healthcare professionals in annual surveys for more than ten years. Among all professionals, the latest Gallup Integrity Poll found that the only ones more trusted than pharmacists were nurses and elementary school teachers.

Surveys help bring strategic knowledge

In order to develop a closer working relationship with pharmacists, CISCRP is planning to conduct two surveys: one for patients and one for pharmacists. The survey results could give insight into how best to create educational material and provide information for the public about clinical trials.

The patient survey will go to patients. It will focus on several areas including: how responsive patients would be to receiving clinical research information from their pharmacist; what type of health and clinical research information do they expect to receive; and what would be the best way for patients to receive pharmacy-directed clinical research information. Eli Lilly & Co. will be funding the patient survey.

Another goal is to prepare pharmacists to speak with patients about clinical trials, including the risks, benefits, and how to find trials in their area.

The pharmacists' survey will attempt to find out how much pharmacists currently know about clinical research, their attitudes and perceptions about the importance of providing clinical research information to patients, how much they currently inform patients about clinical trials, and how receptive



they would be to receiving educational materials on clinical research. This survey will bring a better understanding of how to engage pharmacists in educating patients about clinical research.

Pharmacists' involvement in clinical trials education will benefit patients, clinical trials investigations, and pharmacies. Community members will recognize that their pharmacists can discuss the latest clinical trials as well as standard treatment. This enhanced perception of pharmacists could help drive traffic to pharmacies.

CISCRP is currently seeking additional funding to develop and conduct the pharmacists survey. To talk further about sponsoring the survey, please contact Diane Simmons, CISCRP CEO, at 781-326-3400 or write to info@ciscrp.org.

New bill removes barriers to clinical trial participation

It's challenging enough to find volunteers for clinical trials that test treatments for widespread diseases like cancer and arthritis. It's even harder to find volunteers for trials testing treatments for rare diseases, such as Cystic Fibrosis, Amyotrophic Lateral Sclerosis (ALS), Hodgkin's Disease, and numerous others.

A new bill introduced in the US House of Representatives on June 15, 2009, would make it more appealing for volunteers to enroll in clinical trials for rare diseases. The bi-partisan bill H.R. 2866 would exempt up to \$2,000 of compensation earned from taking part in clinical trials for rare diseases.

The resolution, called the *Improving Access to Clinical Trials Act of 2009*, would apply to people who receive SSI (Supplemental Security Income). Those who receive SSI benefits include people with limited income who are over age 65, blind, or disabled.

While not all clinical trials offer compensation, many do. This exemption is important because compensation from trials could potentially put these volunteers' income over the SSI eligibility threshold. The prospect of losing those benefits could deter many volunteers from enrolling in clinical trials for rare diseases.

The term 'rare disease' or conditions refers to any disease that a) affects fewer than 200,000 people in the US, or b) affects more than 200,000 people in the US, and for which there is no reasonable expectation that the cost of developing and selling the drug will be recovered from sales of the drug in the US. The rare and uncommon diseases are named in the Orphan Drug Act of 1983.

House Resolution 2866 was introduced by Representatives Edward Markey (D-Mass) and Cliff Stearns (R- FL), who co-chair the Congressional Cystic Fibrosis Caucus.

Latest round in the global clinical trials discussion *US FDA Site Inspection Findings, 1997 - 2008, Fail to Justify Global Concerns*

From Clinical Trial Magnifier, Vol. 2: 4 April 2009
Johan PE Karlberg, MD, PhD, BSc

A newly-published study is the newest volley in an international debate over the safety, validity, and usefulness of some



overseas clinical trials sites. A number of scientists consider sites in certain non-US regions well-run and valuable; others disagree.

These study results also fly in the face of a new strategy announced by the European Medicines Agency (EMA). In December 2008, the EMA expressed concern about whether clinical trials conducted by regions outside Europe and North America are ethical and scientifically valid.

Each year, the FDA conducts inspections of trial investigators, sponsors, and IRBs to check their compliance with regulations and to make sure the data submitted is valid and accurate. Karlberg examined 3,818 US Food and Drug Administration inspections of clinical trial sites around the world from 1997 through 2008.

Karlberg's study found that clinical trial sites in Eastern Europe had the lowest number of infractions, followed by the Rest of the World (regions outside of Europe and North America, including Africa, Asia, Latin America, Russia, and others), followed by North America and last, Western Europe.

Among all the investigations, the most common problems reported were "Failure to follow investigational plan" (34.2%); Inadequate and inaccurate records (25.1%), Inadequate drug accountability (9.6%), Inadequate informed consent form (8.9%) and Failure to report adverse drug reactions (8.5%).

PERCENTAGE OF SITES HAVING THREE OR MORE FDA INFRACTIONS

Europe	20.2%
North America	13.4%
Rest of the World	6.5%
Eastern Europe	3.3%* (more than 2 infractions)

Medical Heroes campaign expands into Europe

CISCRP's popular "Medical Heroes" campaign, a multi-media public education effort, will expand into Europe in 2010.

The campaign, which has been broadcast on television and radio, and seen in print in selected US markets, features volunteers shown in their own local environments. The message is "Medical Heroes can be found in everyday places. Volunteers in clinical research are the heroes in the discovery of new medical treatments."

The ad campaign has struck a chord with the public and has raised interest in learning more about clinical trials. Test marketing has shown that when the Medical Heroes campaign runs at the same time as patient recruitment ads, average monthly patient inquiries and enrollment rates at investigative sites increased dramatically.

To build upon these positive results, CISCRP will develop and launch a Medical Heroes campaign for the five major European markets – United Kingdom, Germany, France, Italy, and Spain.

The new European versions of the ads will feature Medical Heroes from each of the five markets. Each country's campaign will also publicize a free phone number for people who want to learn more about clinical trials. Each country will also have educational brochures available.

The US Medical Heroes campaign was developed pro bono by Ogilvy Healthworld, a division of Ogilvy & Mather. The international advertising firm will also create the new public service ads.

CISCRP is seeking additional sponsors to enable the campaign's expansion to European markets. To learn more about sponsor opportunities, please contact CISCRP at info@ciscrp.org or call 1-877-MEDHERO.

AWARE for All debuts in North Carolina

Starting as a single event in Boston, AWARE for All, a free clinical research education program for the public, has blossomed and gained momentum. AWARE for All workshops have now been held annually in Boston, Indianapolis, Philadelphia, Dallas, and most recently, Baltimore in 2009.

The program has been so well-received that it will make its debut in Raleigh/Durham, NC, on September 12, 2009.

The new venue has become a reality thanks to the excellent leadership of Robert M. Califf, MD, Associate Vice Chancellor for Clinical Research, Director of Duke Clinical Research Institute (DCRI) and Professor of Medicine, Division of Cardiology, at the Duke University Medical Center, Durham, NC. Assisting him in this effort is Laura Schanberg, MD, Associate Professor, Co-Chief, Pediatric Rheumatology, also at Duke University Medical Center.

Their enthusiastic efforts were the key to kick-starting the AWARE for All program in Durham. **More than 30 organizations** will participate in the September event to be held at North Carolina Central University.



Robert M. Califf, MD

AWARE for All programs help people learn more about participating in clinical trials, find out what's involved, and share the spirit with people who have participated. AWARE features information sessions and exhibits, a complimentary breakfast reception, and a free lunch with one or more presentations by prominent politicians. All attendees can get free health screenings for HIV, Body Mass Index, Breast and Prostate Cancer, Diabetes, and Vision. Local area residents talk about their participation in clinical research.

Feedback surveys have shown that after attending AWARE programs, fully three-quarters of attendees said that they are more likely to participate in a clinical trial.

CISCRP welcomes professionals who would like to follow in Dr. Califf's footsteps and begin the process of bringing AWARE for All- Clinical Research Education Day to their own community. If you would like to become involved with national expansion of this program, please complete the following online survey: [AWARE for All National Expansion Survey](#).