



Restoring Public Trust in Clinical Research Through Outreach and Education

The restoration of public confidence in clinical research will not occur overnight, but the Center for Information and Study on Clinical Research Participation (CISCRP), an independent, national nonprofit organization, is dedicated to addressing the problem.

The erosion of confidence in the clinical research enterprise is rooted in many causes, including widespread media coverage of industry missteps and tragic errors resulting in harm to patients. These have contributed to an atmosphere of suspicion and doubt that has left the public troubled and confused. The restoration of public confidence in clinical research will not occur overnight, but the Center for Information and Study on Clinical Research Participation (CISCRP), an independent, national nonprofit organization, is dedicated to addressing the problem.

Since its founding in 2004, CISCRP has promoted public trust in the clinical research enterprise by increasing awareness of the industry's role in improving public health. In collaboration with a large and diverse group of industry, healthcare, patient advocacy, government, and research professionals, CISCRP has developed an effective, multifaceted strategy of outreach and education to build public understanding of the clinical research process and the important role participation plays in advancing medical science.

The need for outreach and education is clear: Polls show that 74% of Americans say that they have no “real” knowledge of the clinical research process, and 98% do not know where to access or how to identify and evaluate appropriate clinical studies. Even though the public has been exposed to a tremendous number of recruitment ads, response rates are as low today as they were 20 years ago. Therefore, the first critical step is public education that is not study specific, that addresses the broader benefits of clinical research, and that is collectively embraced by all the stakeholders in clinical research and healthcare.

First Step: Broad Public Awareness

If we are to engage the public, the stage must be set for the message to be heard; doing so requires a national public education media campaign. With *pro bono* support from Ogilvy HealthWorld, a division of the international advertising and marketing agency Ogilvy & Mather, a new public service campaign called “Medical Heroes” has been developed to educate and win over the public about the importance of clinical research participation. During the campaign's year-long development process and extensive focus group testing, strong support was expressed for its easy-to-remember messaging and acknowledgement of the contributions of ordinary people to public health. During screenings before test audiences, the ads were lauded

for their “humanity and emotional appeal,” as viewers declared: “These people are heroes in their own way,” “They’ve done something great for all of us,” and “I see the benefit of [clinical research] . . . to society.”

The Medical Heroes campaign has been test marketed in 30 sites across 18 U.S. markets by Eli Lilly and Company. In the first wave of the market test, a control group of 12 markets that ran their typical recruitment ads was established; in six comparable markets, concurrent Medical Heroes ads were run as well as recruitment ads. The latter markets showed a 38% increase in patient recruitment rates over the control group. The test was repeated, and the results of the second wave showed that response rates to recruitment ads more than doubled in the markets where the campaign was also run. The campaign met its ultimate goal of providing the public with an increased awareness of research participation and an improved perception of clinical research volunteers.

Featuring the stories and images of individuals of different races, ages, genders, and occupations, the Medical Heroes campaign shows how ordinary people make it possible to find cures for disease and advance medical science by their participation. A sample 60-second video is now available on YouTube.com. In the video, a businessman sits down at the counter of a busy diner for breakfast. A waiter comes over to take his order. As the two men interact, the narrator says:

This is Mike. Mike is going to breakfast before he starts his day. What he doesn't realize is that Jim, his waiter, helped save his life. You see, Mike is being treated for heart disease. Ten years ago, Jim volunteered to participate in a clinical study researching a new treatment for heart disease. It was successful, and the new treatment was made available to everyone—including Mike. Like millions of other medical heroes, Jim's participation

in clinical research was a gift to Mike and all people who might benefit from this new medication around the world. Just like Jim, medical heroes can be found in everyday places.

Implementation of the campaign's national media plan will enable it to reach more than 120 million people quarterly through print, radio, and television ads. In order to dramatically increase the reach and frequency of this important public service message, CISCRP will provide the Medical Heroes print, radio, and TV ads to all organizations that contribute to the national campaign, which enables these organizations to run the ads for one year in their local markets.

According to a recent CISCRP survey, many individuals believe that those who raise money for charity by running in a race make a greater contribution to humanity than people who participate in clinical research. Similarly, blood and organ donors are greatly admired by more than twice as many people as clinical research volunteers. Through this broad public education campaign, clinical research volunteers will soon be given the title Medical Heroes that they so richly deserve.

Education Before Participation

Broad public awareness will encourage more people to seek information about clinical trials, prompting a greater need for educational tools in the form of easy-to-read brochures, DVDs, and newsletters. CISCRP has a growing collection of educational brochures that take complex questions about clinical research and put them into everyday language. Foremost among the materials is the “Education Before Participation” series, which is widely used by universities, hospitals, clinical research organizations, boards of health, civic organizations, and community health clinics to educate people about clinical trials and the need for participation.

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Expanding the outreach to minority audiences, CISCRP has also developed customized versions for African Americans and Hispanics. In preparation for the development of these brochures, 20 African American and Hispanic physicians and researchers were interviewed about issues of importance to minority populations. In addition, the brochures' use of language and images was evaluated through mall intercepts in Jackson, Miss.; Springfield, Mass.; White Plains, N.Y.; and San Antonio, Texas. Most of the people interviewed at the malls found the writing easy to understand, and the photos were described as positive and appealing. “It's telling you about what you may have to do in a clinical trial,” commented reviewers. “Clinical trials are important to African Americans,” said others.

The globalization of clinical research has brought home a new challenge for CISCRP: educating people around the world about clinical research participation and what it means to be an active participant in the process. With more than 40% of U.S.-regulated clinical trials conducted overseas, CISCRP has begun to expand its outreach to clinical research participants in other countries—for example, by producing educational brochures in 10 foreign languages. These are based on CISCRP's original “Education Before Participation” brochure, but with a

country-specific list of government, disease-advocacy, and industry resources for residents of 12 different nations, including Argentina, Brazil, Canada (French speaking), Czech Republic, France, Germany, Italy, Mexico, Poland, Russia, Spain, and Ukraine.

By providing valuable information about the benefits and risks of participation, questions to ask, and places to find more information, the “Education Before Participation” series is a valuable tool for beginning the discussion with prospective clinical research volunteers. Clinical research sites have found that these brochures ease the informed consent process.

Beyond the use of educational brochures, there is real value in providing the public with disease-specific educational DVDs. CISCRP has a general market DVD as well as DVDs for African American and Hispanic audiences. All of them use the voices and images of real-life volunteers and healthcare experts. One such video, “New Treatments for Breathing Problems: African Americans & Clinical Trials,” features a woman who struggles with asthma. This video, like the others in the series, offers frank and open discussion of some of the long-standing barriers to minority participation. “People aren’t going to hide information and mistreat you because of your race,” reassures Edgar B. Jackson, Jr., MD, an African American physician and senior advisor to the president and CEO of University Hospitals of Cleveland. “I mean they just can’t do that anymore.”

Produced in collaboration with Public Health Television and academic medical centers and community health centers across the United States, CISCRP’s educational DVDs were created with extensive focus group testing. Input from prominent African American and Hispanic researchers and physicians was obtained to help guide the content and earmark culturally relevant issues as well as ethnomedical values and beliefs. The DVD series targets specific areas, such as clinical research and cancer, diabetes, mental

illness, breathing problems, and heart disease. CISCRP plans to continue the clinical research series with additional disease-specific educational DVDs.

The DVDs have great impact when they are being shown on a loop in waiting rooms, and they can also be posted on websites. Most important is providing prospective volunteers with DVDs to be watched at home—as a tool to help them influence their families and friends who criticize them for choosing to be “guinea pigs.”

Another educational tool is *The Participant* newsletter, which is published by CISCRP every other month throughout the year. *The Participant* focuses on subjects that matter to current and future clinical research volunteers, and provides ongoing information and valuable resources. A look at some recent issues offers insight into *The Participant’s* impact. In one edition, the inspiring story is told of John Cleland, who was successfully treated for metastatic testicular cancer in a clinical trial of the drug cisplatin 36 years ago. In another issue, an article addresses readers’ fears about getting a placebo. Another article explains the process of accrediting human research protection programs and why participants need to know about it.

Community Outreach

Beyond educational tools, outreach is critical to the learning process. CISCRP conducts events entitled “AWARE for All-Clinical Research Education Days” in major cities across the United States. These free, public programs are the culmination of a three- to six-month outreach process.

AWARE brings together disease advocacy groups, hospital and healthcare organizations, educational institutions, and community organizations to provide health information, health exhibits, and free health screenings. In addition, distinguished local politicians, opinion leaders, physicians, healthcare providers, and clinical research professionals serve as keynote

speakers and workshop leaders—all volunteering their time to help educate the public.

In each AWARE location, CISCRP’s outreach efforts take many forms. Active contact is made with 30 to 50 organizational partners, and personal outreach and education are extended to the distinguished members of each city’s Honorary Committee. Local churches, community and health centers, and disease-specific organizations give grassroots support by bringing AWARE’s message directly to their constituents.

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To date, the program has reached more than 160,000 people. AWARE has put a human face on the people who volunteer for clinical trials while building public understanding of the risks and benefits of participating. AWARE is building a movement at the local level, and there is a need to bring this form of outreach to many more communities. When asked whether they are more likely or less likely to participate in a clinical trial after attending AWARE, 75% of the attendees respond, “more likely.”

Helping the Public Find Clinical Trials

With all of the information about clinical research that is available online, what the public wants most can be difficult to find. In a CISCRP survey of more than 4,500 online registry users, respondents explained that they are not concerned about the volume and sophistication of clinical trials data they can find online. Instead, users want easy-to-process trial summaries that help them find trials in convenient geographic locations and contact information for those trials.

These eye-opening findings prompted the development of CISCRP's free public service, www.SearchClinicalTrials.org (SCT). Launched in November 2006 with searches powered by FAST Search & Transfer, this online tool uses sophisticated technologies to scan the web and compile clinical trial listings and results in one location. In addition, SCT allows users to customize

their searches by disease or condition and geographic location; clinical trial sponsors; phase and type; recruitment status; age eligibility requirements; and more. In keeping with CISCRP's goal of increasing public awareness and understanding of clinical research participation and the role that it plays in public health, SCT also provides links to trial results, current medical news, and a list of insightful questions to ask before participating in a clinical trial.

Keys to Success in Restoring Public Trust

Education and outreach are the keys to increasing trust and understanding. Working together across the industry, healthcare, patient advocacy, government, and research professionals can provide educational resources to shift the public's mindset about clinical trials and their participants from confusion and concern to recognition and

appreciation. Although the majority of CISCRP's work to date has been U.S.-centric, anyone who is participating in a clinical trial, no matter in what part of the world, needs to be adequately informed about participation. From CISCRP's point of view, it is time to say "thank you" to the millions of people globally who give the gift of participation each year and to stay committed to educating, informing, and empowering the public about what it means to be an active participant in the clinical research process. **ACRP**

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