

ANNUAL REPORT

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The Center for Information and Study on Clinical Research Participation

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Public Trust in Clinical Research

Restoring public trust in the clinical research enterprise has become an urgent step in improving public health. The exploding demand for safer, more effective treatments for all kinds of illnesses and conditions has led to a growing need for more human subject participation. At the same time, widespread media coverage of industry missteps, poor public understanding of the research volunteer's role, and lack of information about the participation process have contributed to creating an environment in which just 2% of Americans take part in clinical research each year, and 90% of studies are delayed one month or longer due to unfulfilled enrollment.

Who We Are

The Center for Information and Study on Clinical Research Participation (CISCRP) is a first-of-its-kind nonprofit organization dedicated to educating and informing the public, patients, medical/research communities, the media, and policy makers about clinical research and the role each party plays in the process. With support from a broad-based Board of Advisors from industry, healthcare, advocacy, and clinical research, and funding from a wide variety of sources including individual donors, government and research institutions, foundations and corporations, CISCRP has become a respected source for unbiased information about clinical research and what it means to be an active participant in the process.

CISCRP's Mission

- Educate, inform and empower patients, the public, medical and research professionals, the media and policymakers about clinical research participation and what it means to be an active participant in the process.
- Promote greater awareness and understanding of clinical research participation and the role that it plays in public health.
- Facilitate more effective collaboration among all members of the clinical research enterprise.
- Provide resources for the research community to better understand the study volunteer.

Since its 2003 founding, CISCRP has become the public's primary and most trusted source for education about clinical research participation. Using a multi-faceted strategy of outreach and communication, CISCRP is restoring public confidence in the clinical research enterprise and building greater understanding of clinical research's role in improving public health.

Year in Review: CISCRP's Key Accomplishments for 2008-2009

Broad National Awareness

- **AWARE for All-Clinical Research Education Days:** CISCRP has been offering the AWARE program in Boston, Indianapolis, Philadelphia, Dallas, and this year in Baltimore (with the support of the NIH) and with plans in place for a September delivery in Raleigh/Durham. Since the program's inception, CISCRP has amassed an impressive track record of engagement in the program cities. In fact, part of what makes AWARE unique and effective is that CISCRP engages 30 to 50 community partners in each city. Major universities and research hospitals, community health agencies, patient advocacy groups, and grassroots locations such as churches, community centers, and even neighborhood hair salons work with CISCRP to promote the program and educate the community.

According to evaluations of the programs conducted to date, the AWARE model is demonstrating its impact. More than half (53%) of AWARE attendees who never participated in a clinical study prior to the program rated their knowledge of the clinical research process as poor or fair. After attending the AWARE program, 93% rated their knowledge of the clinical research process as good or excellent. Another significant indicator of AWARE's efficacy is that fully three-quarters of attendees said that they are more likely to participate in a clinical trial following an AWARE program. The National Cancer Institute (NCI) offered CISCRP consultation and support in program evaluation by reviewing the current evaluation goals and methods and NCI's Office of Market Research and Evaluation determined that the current questions being used to test knowledge were sound.

Impact measures of AWARE to date:

Community outreach: 269,000 households

Community partners: 580

Attendees: 3,354 (approximately 40% minorities)

Physician/speakers: 234

Honorary committee members: 303

Educational workshops: 97

Going forward, we will implement a national rollout of the AWARE program with the goal of reaching 16 cities over the next 4 years. To help fund this initiative of providing far-reaching, consistent and coordinated public education and outreach, we have submitted an application through the NIH's Recovery Act Grand Opportunities (GO) grant.

- **MEDICAL HERO Rebranding Initiative:** Launched in 2008, this groundbreaking public service campaign (developed pro bono by Ogilvy Healthworld) is transforming the image of the clinical research participant from "guinea pig" to Medical Hero. Using TV, radio and print media to depict the stories of typical clinical research volunteers, the Medical Hero campaign provides recognition for the profound "gift of participation," while raising awareness of the participant's significant contributions to advancing public health. This year's major support came from Hoffman-LaRoche, and a variety of organizations – patient advocacy groups, investigative sites, government agencies, other sponsors and CRO companies – are in the midst of implementing the campaign in the following ways:
 - Where they are already buying print, radio or TV media, they are exchanging 5% to 10% of their recruitment ads with the Medical Hero message.
 - Using the Medical Hero print ads as posters and fliers in the waiting rooms of doctors' offices, hospitals, and community health clinics, and these are placed along side their trial recruitment posters and fliers.
 - Playing Medical Hero radio and TV ads on DVD players in waiting rooms and offices.

- Providing visible links online to the Medical Hero campaign.

As a result of Medical Hero ad placements, CISCRP has been observing a significant increase (35 – 45%) in inquiries by phone and on our website, with CISCRP providing follow-up responses to the public's questions and free educational brochures.

Public and Patient Education and Outreach

- **“Education before Participation” Brochures:** These popular educational materials provide a clear, easy-to-understand introduction to participation for the new and prospective volunteer. Written in straightforward language for a lay audience, the Education before Participation brochures provide the groundwork for further exploration of patient questions and concerns. Targeted versions for minority readers use cultural sensitivity and ethno-medical values and beliefs to address the special interests of African American and Hispanic readers. *Translations into 26 languages with country-specific resources are now available for those conducting trials globally.* A placebo brochure has been introduced for the general public this past year, and our newest publication is for parents who are considering whether or not their children should participate in clinical trials. The key reason companies feel that it benefits them to provide these brochures to their patients is that they ease the informed consent process and provide credibility for specific trials since the general-education component comes from a nonprofit organization. To date, CISCRP has sold approximately 225,000 educational brochures for distribution to the public.
- **Educational DVDs:** Featuring the true-life experiences of real clinical research volunteers, these disease-specific videos describe the participant's role in the clinical research process. Customized DVDs for African-American and Hispanic audiences look at how clinical research participation impacts issues in minority health. These DVDs are perfect to play in a waiting room or to provide to patients as an educational resource for them to play at home; this enables patients to deal with the negative feedback they may receive from family and friends. To date, CISCRP has sold over 7,000 educational DVDs.
- **Medical Heroes Newsletters:** This year we re-launched CISCRP's public newsletter (formerly named “The Participant”) to tie in with the look and feel of the public service campaign. This newsletter reflects our commitment to honor medical heroes, and to provide ongoing education for people considering clinical trials as well as those who have already been involved. This newsletter is sent out on a bi-monthly basis to our emailing list members (or in a print version upon request) to over 22,000 people. Each issue contains: *Medical Hero in the Spotlight*, which profiles a person involved in clinical trials; *Getting Involved: Tips and Advice*, which contains useful information for people considering volunteering; *Your Next Steps*, with information telling volunteers how to remain involved with clinical trials activities after they've participated; and *What's New in Clinical Research*, which will provide timely news and updates about trial results.
- **Search Clinical Trials:** CISCRP has just expanded our online service to include free custom searches for patients requiring additional assistance. The public simply calls CISCRP at 1-877-MED HERO to speak with our staff. We then perform a search to find clinical trials according to the given criteria. Search requests can also be emailed to info@ciscrp.org. The individual provides us with their medical condition, zip code, state or province, distance willing to travel, age and gender and our staff searches dozens of websites and clinical trial registries. We print out the results of our search and highlight key information including the purpose of the study, study name and ID number, eligibility requirements, and most importantly, contact information for the site, investigator or study coordinator. The search results are mailed to the individual along with an educational brochure to help them make

an informed decision about participating in a clinical trial. All search requests are private and all information is strictly confidential. CISCRP is neither recommending nor endorsing any of the clinical trials we find through the Search Clinical Trials service. We are dedicated to educating, informing and empowering those who would like to be active participants in the clinical research process. The website, www.SearchClinicalTrials.org, has received close to a quarter million visitors this past year. And although we have just begun to offer our new consultative service, to date we have conducted customized searches for 150 people.

- **www.MedHero.org** aka **www.ciscrp.org**: CISCRP's website is in the midst of an overhaul to better service the public and patients. We provide a tremendous amount of educational information to our users and this year we recognized the need to provide a social networking feature on our site -- and that has already been implemented. But there is still work to be done to respond to public feedback on website improvements; therefore we are separating the communications for the public from the data specifically prepared for research and healthcare professionals, as well as the Facts & Figures needed by the media. The improved and simplified website will be available to the public at the end of summer 2009. This past year, the www.ciscrp.org website received approximately 264,000 visitors.
- **Post-Study Education**: When clinical research participants are excused from the Study Team, they have a high willingness to participate in another clinical trial, but across the industry there is no follow-up, no sense of connection or assurance of the volunteers' contribution or value. In response, CISCRP is now enabling companies to offer each clinical trial participant a lifetime membership in the Medical Heroes Community. Membership benefits include: free bi-monthly newsletter; invitation to attend a free public education program in their community (AWARE) where they will be recognized as a medical hero and receive a gift; online social network that connects patients, families, friends and caregivers for support and inspiration; assistance in locating other clinical trials; assistance in finding the published results of their clinical trial; and being recognized and honored during the National Medical Heroes Day planned for next year. All these services are provided directly to the patients by CISCRP. Sites incur no additional cost beyond the \$1 per patient for the membership leaflet itself. Patients opt in to the membership service. From the patient's point of view, concerns about follow up and recognition for volunteering will be addressed. From industry's point of view, there is virtually no incremental investment in time with a patient who has completed your clinical trial. This is truly a win-win scenario where CISCRP and industry can collaborate to carry out the mission to educate the public about the clinical research process and promote greater understanding and appreciation of the role of the clinical research volunteer.

Professional Education and Outreach

- **The Participant Newsletter**: This year we re-launched our professional newsletter in order to provide resources for researchers and healthcare professionals to better understand the study volunteer and issues affecting all the stakeholders in the clinical research enterprise. Although the name is the same as the newsletter CISCRP has produced since 2004, the new version of The Participant is written specifically for professionals and supplements the public newsletter now called Medical Heroes. Each bi-monthly issue for professionals presents the patients' perspective as well as industry trends and updates.
- **Researcher Training**: Clinical research professionals develop greater understanding of the clinical research volunteer's needs and desires at CISCRP-sponsored educational workshops. For example, in response to a request from M/C Communications on behalf of Dana Farber, CISCRP has proposed the design and delivery of workshops that demonstrate effective execution of patient education and outreach. The workshops will include case studies as well as educational brochures and DVDs on

clinical research and cancer that are currently used by oncologists at research sites to help ease the informed consent process. M/C Communications is arranging for quarterly offerings of this workshop at each of their Dana Farber Master Class and Clinical Trial Room training programs.

- **Pharmacist Education and Outreach program:** CISCRP's is planning for the distribution of educational materials through pharmacies and for collaborations with APhA and ACCP to prepare pharmacists to speak with patients regarding clinical trials – what they are, the risks, the benefits, and how to find trials in their area. In discussions with the directors of marketing from some of the major pharmacy chains, this interaction has merit in that it could drive traffic to pharmacies; the community will recognize that their pharmacists can counsel them not only on standard treatments, but on the latest clinical trials as well.
- **Presentations at Professional Conferences:** CISCRP staff and Board heightened professional awareness of issues in clinical research participation through a growing number of presentations this past year, including speeches at the national meetings and local chapter meetings of ACRP and SoCRA. In addition, we have presented to clinical research and industry professionals or run workshops at Hollings Cancer Center, Johns Hopkins, Mass General, MUSC, BMS, Pfizer, J&J, Quintiles, AACR, and the National Health Council, amongst many others.

Education and Information–Sharing with the Media & Policymakers

- **AWARE Honorary Chairs and Honorary Committee Members:** Connecting prominent politicians and policy-makers with AWARE's educational programs strengthens CISCRP's visibility on the national stage. Supporters of our AWARE public education program to date include: Governor Rendell, Governor Patrick, Senator Specter, Senator Cardin, Senator Kennedy, Senator Lugar, Congressman Boucher, Mayor Nutter, Mayor Menino, Mayor Peterson, amongst other prominent community leaders.
- **Congressional Briefing:** On June 18th, a congressional briefing entitled "Clinical Research-A Vital Component of Better Health Care" was held jointly by ACRO and CISCRP covering the role of clinical trials in drug development and medical innovation, the importance of individual participation in clinical trials, and trends and challenges in the research process.
- **Speakers Bureau//Media:** CISCRP staff and Board have become a voice for the issue of clinical research participation and play a significant role as public advocates. This year the number of presentations increased significantly including several for the NIH and the FDA. New online chats, plus coverage by consumer press, cable news and professional journals bring CISCRP and its goals to a diverse and growing audience. As examples, CISCRP has written articles and letters to the editor or been cited over the past year in the following media: Los Angeles Business Journal, NY Times, Wall Street Journal, Washington Post, US News & World Report, CNN, www.boston.com, Boston Herald, Urban Update, Daily News Transcript, Chicago Daily Herald, AARP Magazine, press releases from the Stand Up To Cancer telethon, Applied Clinical Trials, eCliniqua, ACRP Monitor, DIA Global Forum, BIO-IT World, www.healthbusinessblog.com, amongst others.
- **National Medical Heroes Day:** The rollout of the Medical Heroes Community membership program will be supported by a media event recognizing and celebrating those who have given the gift of participation. The plan is for a full-blown PR campaign with press releases, feature stories (radio, newspaper, and B roll for TV coverage), plus full page ads thanking clinical research volunteers. Medical Heroes awareness packs will be provided to the media, and promotional items like our

Medical Hero buttons will be provided directly to consumers. The plans are being developed to hold the National Medical Heroes Day at the end of next year.

Scholarly Research Projects

- **Public Surveys:** These benchmark and ongoing measures are important tools for assessing trends in public perceptions of clinical research participation. They are used to guide CISCRP's development of new educational initiatives and to provide the industry with better knowledge of the volunteers' experiences in clinical research. Here are examples of surveys being planned with support from 2 major sponsors: A Patient Survey will focus on a number of areas including, but not limited to: what type of health and clinical research information and how patients receive that information from pharmacists today; patient receptivity to receiving clinical research information from their pharmacist; and perceptions around the ideal content, format and distribution of pharmacy-directed clinical research information to patients. In addition, a Pharmacist Survey will be conducted among a variety of pharmacists including those in independent and chain store community-based practices, academic and health system settings, and those in managed care organizations and clinics. The pharmacist survey will focus on several areas including, but not limited to: what pharmacists currently know about clinical research; their attitudes and perceptions about the importance of providing clinical research information to their patients; current practices with regards to informing patients about clinical trials; and their receptivity to receiving educational materials on clinical research.
- **Focus Groups:** CISCRP conducted three focus groups in March 2009 in Winston-Salem, NC. The focus groups are part of an ongoing effort to gather primary research and gain a deeper understanding about study participants. CISCRP is preparing a White Paper that discusses the focus group findings in more detail, but the preliminary findings were published in the initial issue of CISCRP's professional newsletter, *The Participant*, in the May 2009 issue.
- **Pilot study to develop clinical trial results summaries:** CISCRP has been funded to evaluate study volunteer comprehension of clinical trial results summaries; to anticipate study volunteer responses following their review of the summaries; and to identify the most efficient and effective distribution methods to position these summaries. Ultimately, this pilot study will assist the industry in anticipating potential issues prior to the introduction of FDAAA guidelines mandating non-technical clinical trial results summaries. This pilot study will also assist the sponsor in establishing a formal mechanism and process to develop and distribute lay summaries of clinical studies across their portfolio.

What's Being Said About CISCRP

CISCRP fills an important void in educating the public about the value of clinical research and its importance in advancing public health. The goals of all members of the clinical research enterprise – academia, government, industry, patient advocacy organizations, and society in general – are supported by CISCRP's programs and initiatives.

James P. Kremidas, Vice President
Global Head of Patient Recruitment
Quintiles, Inc.

CISCRP is uniquely positioned to provide a balanced view of the conduct of clinical trials and the overall benefits they bring to society. CISCRP helps educate all the key parties (i.e. general public, practicing physicians, regulatory and policy authorities, and the press) on the need to encourage well-informed participation in clinical trials as well as provide due recognition to those who volunteer.

Jorge G. Guerra, MD, FACP, Senior Vice President
Global Clinical Operations
Biogen Idec

I am pleased to represent the National Health Council on the CISCRP Board of Advisors. The organization is working hard to increase trust in, and the effectiveness of the clinical research process. It is my sincere hope that other organizations involved directly or indirectly in clinical research will support CISCRP in its efforts.

Myrl Weinberg, CAE, President
National Health Council

The single most important and effective step toward improving the quality and safety of clinical research is to better inform the public. CISCRP is the only organization of its kind and plays an essential role in this process of providing education and information for research participants through its novel programs, like Aware for All. Informed participants demand that clinical research be done well, and when it is, everyone wins.

Greg Koski, MD, PhD
Senior Scientist, Institute for Health Policy
Massachusetts General Hospital and
Associate Professor of Anesthesia, Harvard Medical School

Duke University Clinical Research Institute is proud to be a member of the CISCRP Circle of Supporters because we believe that the wide array of initiatives provided by CISCRP will be a great asset to the public, patients, and those taking part in clinical research.

Dr. Robert Califf, Director
Duke Clinical Research Institute

I believe CISCRP's outreach initiatives will serve an important role in educating and informing the public about the clinical research process and the role that clinical research participation plays in the advancement of medical science.

Nancy Zeleniak, Global Head
Venture Relations
PPD Development

I applaud the efforts of the Center for Information and Study on Clinical Research Participation in educating the public and patients about the importance of clinical trials and the vital role they play in improving public health.

US Rep. Rick Boucher (D-VA)
Sponsor of House Resolution 248
Honoring the Contributions of Clinical Trial Participants

CISCRP's programs, particularly the release of the Public Service Announcement, address a long-standing need to raise awareness and increase understanding and trust of the clinical research process.

Dr. Bernard Schwetz, DVM, PhD, Former Director
Department of Health and Human Services
Office for Human Research Protection