

# ANNUAL REPORT

## 2009-2010



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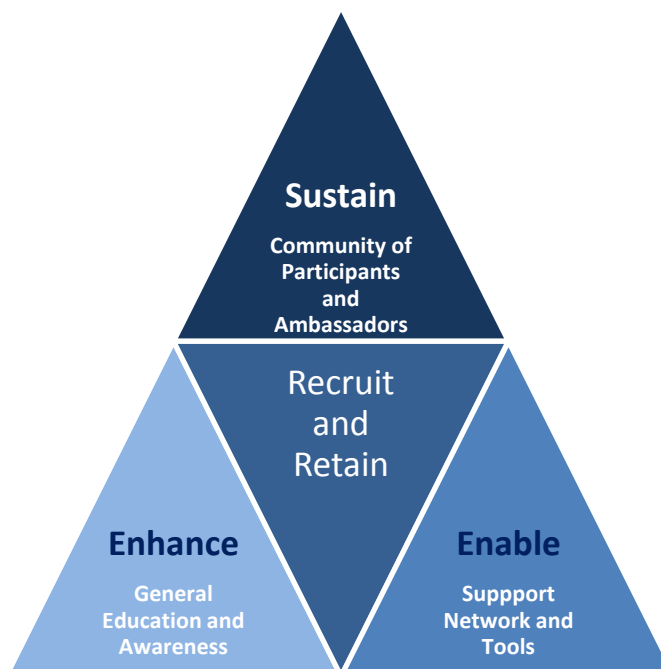
[www.ciscrp.org](http://www.ciscrp.org)  
[www.medhero.org](http://www.medhero.org)

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## 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.

*How can a durable relationship be built with the millions of past, present and potential future clinical research study volunteers? A portfolio of strategic initiatives (as shown in the model below) is needed to regain public trust in the clinical research enterprise and establish a culture that welcomes input from patients. Since its founding in 2003, the independent nonprofit Center for Information and Study on Clinical Research Participation (CISCRP) has developed an effective, multi-faceted strategy of outreach and education to improve public understanding of the clinical research process and the important role participation plays in advancing medical science.*



**Figure 1: CISCRP's model for a portfolio of strategic initiatives to regain public trust in the clinical research enterprise**

*If general education and awareness of the clinical research process are enhanced, and if patients are enabled to participate because of the support network and tools provided to help them become active participants in clinical trials, then issues with recruitment and retention in trials will improve. With this solid foundation, volunteers will become a community of participants and ultimately the ambassadors of a process that advances medical science and improves public health.*

## Executive Summary

The excitement about CISCRP's mission continued this year as our Circle of Supporters grew to 362 organizations representing a broad group of stakeholders from clinical research and healthcare. Here are highlights of the strategic initiatives made possible by their support:

- ✦ Widely-read educational resources about the clinical research process were provided to the public through a supplement in the *Wall Street Journal* and the *Merck Manual*.
- ✦ Free iPod app, *A Guide to Clinical Trials*, was launched.
- ✦ *The Gift of Participation* was entered into circulation at public and medical school libraries across the US.
- ✦ Customized searches for clinical trials were conducted for over 1100 prospective volunteers who received assistance in locating trials along with free educational materials.
- ✦ AWARE grassroots public education programs were repeated in Boston, Philadelphia and Baltimore and we introduced three new cities – Nashville, Raleigh-Durham and San Diego.
- ✦ CISCRP's *Medical Hero* public education media campaign continued with print, radio and TV ads supplemented by distribution of 26,000 Medical Heroes newsletters, 10,000 Medical Hero membership packets, and thousands of posters and buttons.
- ✦ A *National Clinical Research Education Day* was designed as a live webcast, set to launch this coming November.
- ✦ CISCRP's new catalog of programs and resources was designed and distributed, increasing sales of educational print and digital materials to hundreds of new organizations.
- ✦ Pilot test was completed of a new process for routinely communicating clinical trial results to study volunteers after their participation has ended.
- ✦ Survey was conducted of 2650 patients' perspectives on receiving information about clinical research from their pharmacist.
- ✦ Focus groups were held among study volunteers to attempt to answer the question about how to improve patient recruitment and retention rates; results published in whitepaper.
- ✦ Special event with John Crowley (whose story inspired the movie "Extraordinary Measures") continued CISCRP's partnership with the DIA to connect the patient's voice directly with DIA's more than 18,000 members; each issue of the DIA's Global Forum carried a story from the patient's perspective provided by CISCRP.

Broad National Awareness

- **MEDICAL HERO Rebranding Initiative:** This year's major support for CISCRP's public education media campaign came from **Pfizer, Johnson & Johnson** as well as **The Community Foundation**, and a variety of organizations – patient advocacy groups, investigative sites, other sponsors and CRO companies – implemented this groundbreaking campaign developed pro bono by Ogilvy Healthworld in 2008. The campaign 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. As a result of Medical Hero ad placements, CISCRP has been handling an increasing number of inquiries by phone and email (over 1000 contacts/month), with CISCRP providing follow-up responses to the public's questions, free educational brochures, and assistance in locating trials.
- **National Clinical Research Education Day:** CISCRP has plans in place to host a live national webcast of our “AWARE for All” education program on Saturday, November 6 from noon to 2pm EST. The webcast features a presentation by CISCRP founder Ken Getz entitled “What Clinical Research Means To You” and a panel of patients who have participated in clinical trials. A growing number of sponsors, universities and research hospitals, disease advocacy groups, community health agencies, community centers, and faith-based groups have signed up so that their constituents can view this informative program directly from their facilities. All that is needed for organizations to participate is a phone line, internet connection and a projector/screen. The organizations log-in via the web and host the program locally as part of this nationwide effort to educate the public.

Public and Patient Education and Outreach

- **Catalog of Programs and Resources:** With pro bono support from **D. Anderson and Company**, CISCRP was able to provide information on our educational programs, brochures, DVDs, posters and more to hundreds of organizations interested in public and patient education and outreach. DAC assisted CISCRP with the design and production of a comprehensive catalog. This communications resource not only positioned the value of the CISCRP mission, but the professionalism of the catalog made possible a significant increase in the distribution of CISCRP's educational tools by attracting interest from new disease advocacy groups, research sites, academic institutions and corporations.
- **iPod App:** CISCRP has introduced *A Guide to Clinical Trials*, an iPhone app that provides answers to critical issues about the clinical research process. The app includes a variety of educational materials, an online search tool for finding clinical trials and one-touch access to CISCRP's programs/services.
- **Public and Medical School Libraries:** An anonymous donation made it possible this year for CISCRP to arrange for the book *The Gift Of Participation – A Guide to Making Informed Decisions About Volunteering for a Clinical Trial* to be entered into circulation at hundreds of libraries across the US. We have received enthusiastic responses from librarians, as shown by this example: “I believe this book will enhance our collection and be a valuable source of information to the citizens of Utah.”
- **Merck Manual:** The Merck Manual 2010 has a new chapter about clinical research with CISCRP prominently referenced.

- **AWARE for All-Clinical Research Education:** The AWARE model has a 5-year history in 15 cities, reaching more than 369,000 households and 760 community partners. In 2009-2010 we repeated our program offerings in Boston, Philadelphia and Baltimore and introduced three new cities – Nashville, Raleigh-Durham and San Diego. CISCRP’s grassroots educational outreach model responds to the severe shortage of volunteers participating in clinical research studies by addressing the public’s lack of fundamental knowledge about clinical research and low level of trust. AWARE offers a significant improvement over traditional public education that is short-term; once enrollment targets have been reached, these programs are terminated. They fail to provide far-reaching, consistent and coordinated public education and outreach. In contrast, AWARE offers an educational tool that is driven by the premise that awareness, realizing the value of participation, and ongoing engagement are the keys to generating public support and attracting more clinical research volunteers. Therefore, AWARE is a 3- to 6-month outreach and education process per community that culminates in a free one-day public program. AWARE involves grassroots coalition building between health care organizations and community groups; it addresses the unique dimensions of disparities in access to trials and it promotes the important contributions of clinical research volunteers. It provides the context to make informed choices about participating and finding appropriate trials.
- **Speakers Bureau:** CISCRP offers access to speakers for community groups. Speakers include members of CISCRP’s Board and staff, members of the clinical research and medical community, as well as individuals who have taken part in clinical research studies. CISCRP recognizes that a presentation by someone in the local community creates enhanced trust, credibility, and connection so we begin with local speakers who are able to share their knowledge and experiences with the public in an informative and engaging style. CISCRP provides a PowerPoint presentation template with background information and statistics which speakers customize. This past year, CISCRP’s Speakers Bureau accommodated over a dozen community groups.
- **“Education before Participation” Brochures:** To date, CISCRP has sold close to 360,000 educational brochures for distribution to the public. These popular educational materials provide an 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 24 languages with country-specific resources are now available for those conducting trials globally. In addition, the placebo brochure (*What is a Placebo-Controlled Clinical Trial?*) and the *Children In Clinical Studies* brochure (for parents who are considering whether or not their children should participate in clinical trials) have also been translated this year into French, Russian, Ukrainian, Slovak, Finnish and Afrikaans. 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.
- **Educational DVDs:** CISCRP has sold over 8200 educational DVDs featuring the true-life experiences of clinical research volunteers. These disease-specific videos, developed from a partnership with Public Health Television and academic medical and community health centers, describe the participant’s role in the clinical research process. To date they have been produced for patients with breast cancer, lung cancer, prostate cancer, ovarian cancer, leukemia, multiple myeloma, allergies and asthma, COPD, diabetes, bipolar disorder, depression, GAD and heart disease; and they have been customized for African-American and Hispanic audiences with a look at

how clinical research participation impacts issues in minority health. The DVDs are being used by academic medical centers, community health centers, research sites, pharmaceutical companies, and CROs to bring more people, including minorities, into the mainstream of clinical research participation. The DVDs are played in waiting rooms or given to patients as an educational resource to play at home, thus enabling patients to deal with negative feedback from family and friends about their decision to participate in a clinical trial.

- **Medical Heroes Membership packets, Newsletters, Posters and Buttons:** This year, CISCRP expanded the number of ways in which to honor and educate former and prospective clinical research volunteers as Medical Heroes. Over 10,000 volunteers received a Thank You in the form of a Medical Hero Membership packet entitling them to all the privileges of membership – free newsletters, a social network, AWARE programs, etc. The *Medical Heroes* newsletter was sent out on a bi-monthly basis to our 26,000 contacts via email (or in a print version upon request). Each issue included: *Medical Hero in the Spotlight*, which profiled a person involved in clinical trials; *Getting Involved: Tips and Advice*, which contained 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 provided timely news and updates about trial results. In addition to the newsletter, CISCRP disseminated 7000 *Medical Hero* posters and 3000 buttons to those institutions that supported us in reinforcing the Medical Heroes message.
- **Search Clinical Trials:** With support from **ePharmaSolutions**, CISCRP expanded our online service to include free custom searches for patients requiring additional assistance. When the public calls CISCRP at 1-877-MED HERO or submits an online request at [www.searchclinicaltrials.org](http://www.searchclinicaltrials.org), we perform a customized search to find clinical trials according to the given criteria. We print out or email 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 staff. 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](http://www.SearchClinicalTrials.org), has received over a quarter million visitors this past year. And we have conducted customized searches for 1,100 people.
- **www.MedHero.org aka www.ciscrp.org:** CISCRP's website underwent an overhaul this year to better service the public and patients. We are providing a tremendous amount of free educational information to our users and a social networking feature ("Clinical Research Volunteers community"). We separated the communications for the public from the data specifically prepared for research and healthcare professionals and the media. The improved and simplified website was launched at the end of summer 2009 and received approximately 276,000 visitors this year.

#### Professional Education and Outreach

- **Patient Perspective in DIA Global Forum:** CISCRP created a series of articles that appeared in the DIA publication circulated to 18,000 members. This series is part of our educational awareness campaign that those who volunteer in clinical trials are genuine "Medical Heroes." Each story is intended to help the research and healthcare professional better understand the clinical trial volunteer and captures the experiences (both positive and negative) of real patients who have been involved in clinical trials.

- **The Participant Newsletter:** CISCRP's *The Participant* is written specifically for professionals and supplements CISCRP's public newsletter called *Medical Heroes*. Each issue presents the patients' perspective as well as CISCRP updates to remind contributors and prospective donors how their funds are being used to carry out our mission of educating the public about the clinical research process and building trust in the clinical research enterprise.
- **Researcher Site Staff Training:** Clinical research professionals develop greater understanding of the clinical research volunteer's needs and desires at CISCRP-sponsored educational workshops. For example, CISCRP recently presented at a clinical research coordinators workshop for Dr. John Baron's Vitamin D/Calcium Polyp Prevention Study Section of Biostatistics & Epidemiology at Dartmouth Medical School. At this workshop, the coordinators considered novel ways in which to embrace the Medical Heroes campaign. They reviewed and incorporated CISCRP's educational resources and volunteer membership program with the goal of improving upon their own patient education/retention efforts.
- **Pharmacist Education and Outreach program:** CISCRP launched an initiative for public outreach through pharmacies and a critical next step is collaborating with such organizations as 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. With funding provided by a grant from **Eli Lilly & Co.**, CISCRP gathered data on patient receptivity to pharmacy-directed clinical research educational resources. (See details in "Scholarly Research Projects" below.) Results of this public survey suggest that pharmacists could meet an unvoiced patient need by providing clinical research educational resources; and that pharmacy-directed outreach strategies could strengthen the pharmacist-patient relationship and become a crucial lever point in turning around public perception and understanding of the clinical research process.
- **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 and meetings at the FDA and the Institute of Medicine, as well as 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 Johns Hopkins, Mass General, Bristol-Myers Squibb, Pfizer, and the American Association for Cancer Research, 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. Supporters of our AWARE public education program to date include: Governor Rendell, Governor Patrick, Lieutenant Governor Brown, Senator Specter, Senator Cardin, Senator Kennedy, Senator Lugar, State Senator Davis, Congressman Boucher, Mayor Bell, Mayor Dixon, Mayor Nutter, Mayor Menino, Mayor Peterson, amongst other prominent community leaders.
- **FDA Briefing:** CISCRP met with the FDA regarding patient access to trial results for the purpose of integrating FDA feedback with lessons learned from CISCRP's interviews with investigators, study coordinators, IRB members and focus groups with patients. The goal was to work towards identifying best practices for providing patient access to trial results for consideration by all sponsors.

- **Institute of Medicine:** CISCRP presented at IOM's Learning Healthcare System workshop and a manuscript of this presentation will soon be published by IOM as "Enhancing the culture of patient contributions to learning in health care."
- **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 continues to increase 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: Wall Street Journal, Los Angeles Business Journal, NY Times, Washington Post, US News & World Report, CNN, Boston Herald, Urban Update, Daily News Transcript, Chicago Daily Herald, AARP Magazine, Applied Clinical Trials, eCliniqua, ACRP Monitor, DIA Global Forum, BIO-IT World, amongst others.
- **National Medical Heroes Day:** We are preparing for the rollout of National Medical Heroes Day as a major media event recognizing and celebrating those who have given the gift of participation. We are lining up a full-blown PR campaign with press releases, feature stories (radio, newspaper, and TV coverage), plus full page ads thanking clinical research volunteers. Medical Heroes "awareness packs" are being developed for distribution to corporations and the media, and promotional items like our Medical Hero buttons will be provided directly to consumers. The target date for National Medical Heroes Day is in June 2011.

#### Scholarly Research Projects

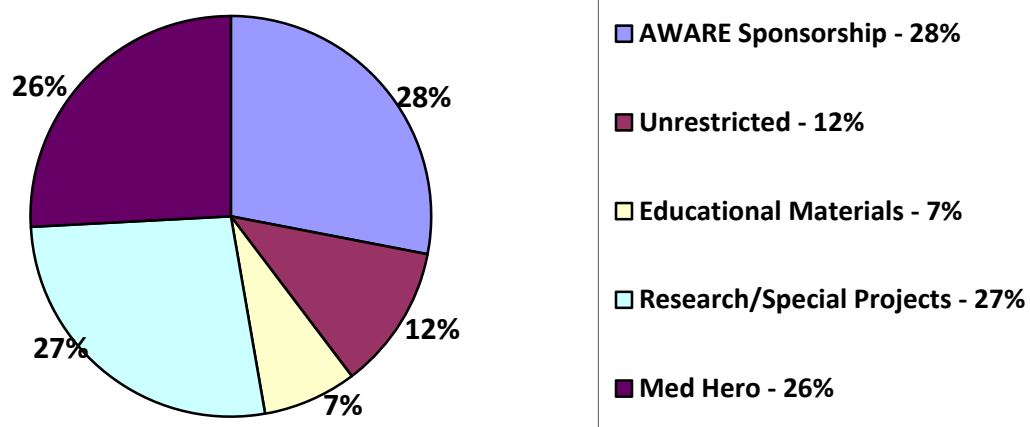
- **Public Survey on Receptivity to Pharmacy-Directed Clinical Research Educational Resources:** It was hypothesized that pharmacists represent an untapped resource to raise patient awareness with respect to clinical research. Funded by a grant from **Eli Lilly & Co.**, this study examined, via survey, patients' perspectives on receiving information about clinical research from their pharmacist. An analysis was made of 2,650 questionnaires completed online between 4/2 and 4/26/2010, by members of online social networks from 54 public/patient organizations. Nineteen questions assessed respondent demographics and three interest areas: (1) current health and clinical research information received by patients from pharmacists; (2) patient receptivity to clinical research information delivered by pharmacists; and (3) perceptions around ideal content and distribution method of this information. Analysis indicated statistically significant differences in interest and need by demographic group; however, all pharmacy users desired information at rates greater than 77%, regardless of age, gender, education, type of pharmacy used, or location. Respondents also indicated clear preferences about the content and delivery method of clinical research information from their pharmacist.
- **Focus Groups on Factors that Most Inform and Educate Clinical Research Participants:** In an attempt to answer the question about how to improve patient recruitment and retention rates, CISCRP conducted focus groups among study volunteers to probe for factors that most inform and educate clinical research participants. This research was conducted at **Piedmont Medical Group** in North Carolina. In these focus groups, participants reasserted the essential role that study staff and health care professionals play in volunteer recruitment and retention. They consistently described relationships with study staff as tough but fair; disciplined but supportive. At a time when recruitment and retention strategies and tactics tend to marginalize the role of the study staff and trusted health care professionals, the results of these focus groups strongly suggest the need to more effectively

engage these professionals as real assets in the clinical trial process. The focus group participants revealed core motivations of all study volunteers regardless of age and socioeconomic status. These motivations can serve as a blueprint for patient and public education and outreach.

- **Pilot Study to Develop Clinical Trial Results Summaries for Patients:** CISCRP and **Pfizer** collaborated to test a new process for routinely communicating clinical trial results to study volunteers after their participation has ended. Between June and December 2009, trial results for Celebrex®/Celecoxib and Sutent®/Sunitinib were translated into lay language by a team of consumer, science and medical writers and published in three print, web and audio formats. These summaries were then tested in focus groups among volunteers who had participated in the studies. The pilot study results demonstrate that a process for preparing and disseminating trial results summaries to patients following their participation in clinical trials is feasible. Moreover, patients reacted very positively to the variety of formats and showed marked improvement in their comprehension of their clinical trial findings. Study personnel are also very receptive to disseminating trial results summaries to their study volunteers.
  
- **Beta Test to Develop Clinical Trial Results Summaries for Patients:** In light of the promising Pilot Study results, CISCRP and **Pfizer** have embarked on a larger scale study to further evaluate and refine the formal mechanism and process to develop and distribute lay summaries across Pfizer's portfolio. Much time may pass between the study volunteers' last visit and the receipt of the trial result summary. Therefore it is important to continue to engage the volunteers in the process so they remain informed and continue to realize the important role they play in clinical research. To achieve this result, CISCRP will prepare a communication in the form of a "thank you" message with a study-specific note to be distributed at the patients' last visit. This communication will set up expectations of when the study volunteers should receive the trial results summary; it will also mention periodic updates that will be sent to them in the meantime. The site staff will receive instructions from CISCRP on the use of these communications and answers to potential questions from patients. IRB involvement will be explored. *It is our hope that all trial sponsors will embrace the notion that research participants are entitled to know the outcome of their studies and will actively work to provide them with the information. Doing so represents an ideal opportunity for sponsors to acknowledge volunteers' generous gift of participation.*

## Financial Overview for 2009-2010

CISCRP is in good financial health in 2010 and poised for growth. In the face of the economic downturn, CISCRP was fiscally responsible, remained lean on staffing and moved offices to Boston to recognize cost savings versus previous year. Contributions are up by close to 20% over previous year levels. In addition, CISCRP continues to diversify its portfolio of funding sources to include higher proportions of grants for research and special projects; sales of educational print and digital materials; and contributions specifically for the Medical Heroes public service campaign and the AWARE public education programs.



CISCRP's annual funding comes from a variety of supporters including clinical research professionals, pharmaceutical and biotechnology companies, contract research organizations, trade and health associations, health care providers, and foundations. Some 362 organizations are now Circle of Supporter Members.

Major funding growth drivers in 2010/2011 include the National Clinical Research Education day webcast; the Medical Heroes Campaign; and special projects including an exciting new initiative for CISCRP to translate listings from [www.clinicaltrials.gov](http://www.clinicaltrials.gov) into lay language that can be distributed to study participants after clinical trials have ended.



*The Center for Information and Study on Clinical Research Participation (CISCRP) is a first-of-its-kind nonprofit organization. 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 participation.*

### **CISCRP BOARD OF ADVISORS**

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