

THE PARTICIPANT

VOLUME 2 ■ ISSUE 2



THE PATIENTS' PERSPECTIVE

CISCRP, Pfizer Pilot Program to Provide Volunteers with Study Results

What were the results of the clinical trial in which I participated? How are the results being used? Did my participation really matter?

For clinical trial participants, these are important questions. Few participants hear from study staff – or any party – once their participation has ended. And according to focus groups, of those study volunteers who first learn about the results of their clinical trials through the popular press, many feel slighted by not having received a description of the results prior to a public announcement. But for sponsors, the prospect of providing volunteers with lay-language results has proved more daunting.

CISCRP and Pfizer Inc. recently completed a pilot project to investigate whether it's feasible to translate highly technical clinical language into "plain English" summaries and to see how participants and investigators reacted to the summaries. The findings, which will soon be published in a leading journal, show that technical results can be communicated in everyday language and that these summaries were well received by both volunteers and researchers.

Between June and December 2009 CISCRP's medical and consumer writers translated technical summaries from two studies posted on <http://clinicaltrials.gov> and <http://clinicalstudyresults.org>. Results from a Celebrex®/Celecoxib trial for the

treatment of osteoarthritis and a Sutent®/ Sunitinib malate trial for the treatment of stomach cancer were translated into sixth- to eighth-grade reading level. Summaries were prepared in three formats – a brochure, a webpage and an audio cast – each of which presented the same core information. Pfizer staff reviewed the translations and provided input into their scientific accuracy.

The summaries were then evaluated by study participants and researchers who worked on the trials. Thirteen trial volunteers from the Celebrex study provided feedback via focus groups. In light of the cancer patients' deteriorating health, doctors treating patients who had participated in the Sutent study provided informal feedback on their reaction to the summaries.

Focus group participants reacted favorably to the summaries. They liked the written report best, followed by the webpage, but considered the audio format an important option for "non-readers." They stressed the need to provide results in multiple formats to accommodate different learning styles.

In terms of content, focus group participants said they want concise, easy-to-read summaries that encapsulate what happened and why. They want the summaries to describe the results of the trial and how those results will be used. They also want the summaries to acknowledge the participants' role in

advancing medical science and to direct participants to additional information should they want to ask questions or follow up with study staff.

Converting certain technical and scientific language to a sixth-grade reading level – as measured by the Flesch-Kincaid readability score – posed a challenge and a degree of precision was lost in the simplified summaries. Despite that drawback, pre- and post-summary tests administered to focus group participants showed the summaries clearly augmented their understanding of the trial, its objectives, side effects and key findings.

Study staff members were enthusiastic about the pilot. Having a neutral third-party develop and disseminate the summaries conveyed credibility and balance, they said, and would likely enhance volunteers' trust in the clinical trial process.

In light of the promising 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.

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.

News from CISCRP

Wall Street Journal Supplement Highlights Clinical Trials

In April, Media Planet published a special four-page publication on clinical trials featuring an introduction by CISCRP founder and board chair Ken Getz. The supplement was sent to 2.5 million subscribers of the Wall Street Journal. To read the supplement, please visit http://doc.mediaplanet.com/all_projects/4921.pdf.

Upcoming Clinical Research Education Days

CISCRP will sponsor AWARE for All events in Durham, Baltimore and San Diego this fall.

AWARE for All is a free event that enables the public to learn more about the clinical research process. The events will be held:

- **Saturday, September 25** at North Carolina Central University in Durham, NC
- **Saturday, October 23** at Johns Hopkins University in Baltimore, MD
- **Saturday, November 13** at the Salvation Army Kroc Center in San Diego, CA

Surveys show that after attending an AWARE session, 75 percent of attendees say they are more likely to participate in a clinical trial. For more information please visit www.awareforall.org or email aware@ciscrp.org.

iPhone app links public to clinical trial

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 tools, an online search tool for finding clinical trials and one-touch access to CISCRP's programs and services.

Special Event at the DIA

CISCRP invites conference participants at the Drug Information Association's 46th annual meeting to attend a special presentation by John Crowley, whose story inspired the movie *Extraordinary Measures*.

Mr. Crowley's children suffer from Pompe Disease, a rare neuromuscular disorder. During his presentation, "Voices of Medical Heroes: A Family's Journey of Hope," he will retell the story of how he and his family navigated the challenging clinical trial process and offer his unique perspective on the real medical heroes.

The presentation will be held Monday, June 14 from 6:15-7:15 p.m. in the Ballroom of the Walter E. Washington Convention Center in Washington, D.C. For more information, please contact: info@ciscrp.org or 617-725-2750.

Since 2007, CISCRP has partnered with the DIA to connect the patient voice directly with DIA's more than 18,000 members.

November 6 is National Clinical Research Education Day

In honor of the first annual National Clinical Research Education Day, CISCRP will host a live national webcast of its "AWARE for All" education program Saturday, Nov. 6 from noon-2 p.m. EST. AWARE is one of CISCRP's most ef-

fective outreach and educational tools designed to address the public's lack of understanding and distrust of the clinical research process.

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.

We encourage you to invite patients and members of the community to your facility to view this informative program. All you need is a phone line, internet connection and a projector/screen. You'll log-in via the web. For more details and to register, please visit www.awareforall.org, call 1-877-MED-HERO or email aware@ciscrp.org.

Become a member of CISCRP's Circle of Supporters

If you value CISCRP's mission to educate and empower people so they can make informed decisions regarding participation in clinical research, please consider joining our Circle of Supporters. Make a donation now and we'll provide you with additional resource materials for National Clinical Research Education Day. To make a donation, please visit www.ciscrp.org and click on "Support Us."