
CISCRP Board of Advisors Meeting

(excerpt from December 14, 2010)

MINUTES

Participants: Ken Getz (Chair); Diana Anderson, Bonnie Brescia, Rob Califf, Joan Chambers, Scott Connor, Peter DiBiaso, Sarah Ebner, Courtney Gray Haupt, Felix Gyi, Lani Hashimoto, David Knepper, Greg Koski, Jim Kremidas, Tim La Croix, Mark Lacy, Christine Pierre, Linda Strause; CISCRP Staff: Diane Simmons, Jill McNair, Zachary Hallinan, Emily Ouellette

Welcome and Meeting Overview

Diane opened the meeting and confirmed the attendance of those present in Boston and those joining via phone conference. Diane provided an overview of the meeting schedule and content.

Overview of CISCRP's 2010 Key Accomplishments

CISCRP Staff provided updates on the programs and resources delivered over the past year:

- *Medical Heroes* public service campaign increased reach and frequency; however, we are still falling short of our goal for this campaign which is to become top-of-mind with more TV, radio and print ads. We have had major sponsors like Genzyme embrace the campaign, giving the ads to 100 sites across the US and Canada, and that kicked up the visibility. In addition, independent sites continued to approach us for use of the campaign to augment their recruitment strategy.
 - Through the personalized service called *Search Clinical Trials*, CISCRP conducted over 100 searches per month; approximately 1800 to date. CISCRP provided patients with search results and with educational tools (brochures, newsletters, etc). We would like to promote this service and set up the infrastructure to handle substantial expansion.
 - On the promotional side, CISCRP achieved significant visibility through the Wall Street Journal supplement that provided basic information on clinical research to the public. In addition, the Merck Manual chapter on clinical trials reached millions, and the patient stories provided by CISCRP in each issue of the DIA Global Forum touched all their members.
 - On the research front, primary research was conducted on public interest in receiving clinical trial info from pharmacists. This was a major survey with 2600 respondents; results are that the public doesn't currently ask their pharmacist but would like to ask about clinical trials since pharmacists are highly trusted. Lilly funded this project, and a peer-reviewed article on this initiative was prepared for publication in 2011. (Felix flagged the need for a cross-section of pharmacists to survey and suggested connecting with Bernie Schwetz for his history on pharmacy-related projects.)
 - In a Pfizer pilot test on clinical trial results for the public, we explored the feasibility of providing lay summaries to volunteers. The Board was directed to the article in *Applied Clinical Trials* that detailed the pilot study (copies distributed). Piggybacking on the process that is in place for sponsors to develop the clinicaltrials.gov results postings, CISCRP worked with a panel of writers to produce scientifically accurate trial result summaries at 6th to 8th grade level in 3 versions - print, audio, webpage - so as to accommodate different learning styles. Investigators were interviewed as part of this study and they talked about the value of this initiative in terms of increasing patient trust and understanding. They also pointed out that CISCRP, as a neutral third party, provided credibility. The pilot demonstrated that patient comprehension increased. In focus groups, some volunteers reported that they did not remember their trial experience and CISCRP is now testing a process to engage them
-

CISCRP Board of Advisors Meeting

earlier with a series of communications, starting at the patients' last visit and continuing at intervals until the trial results are ready for publication. All of the communications that go out to study volunteers were delivered by the study staff and CISCRP prepared the study staff to answer patient questions.

The potential for this service is huge. In preparing for scalability, CISCRP is engaged by Pfizer to conduct a beta test to consider how to roll out this process to their portfolio and we are having conversations with other sponsors. The sponsors agree with our strategy of creating non-promotional communications that thank volunteers for helping to advance medical science.

The issue was raised about providing patients' personal results in addition to the lay summaries. CISCRP's position on this issue is that the patients have a right to know which arm of the study they were in and whether or not they were on a placebo. Until this data is made available to the patients, CISCRP is going to continue to teach patients about the clinical research process and empower them to ask questions while we prepare the sites to answer their patients' questions and concerns about trial results. CISCRP Staff agreed to follow up with Linda and Christine to further discuss the sites' issues and how to balance the needs of the volunteers and the sponsors.

- This was the year of AWARE becoming a National program, with over 800 attendees, through the introduction of the webcast model. The webcast supplemented the delivery of live programs in Nashville (Vanderbilt), Philadelphia (4th year), Baltimore (Johns Hopkins), NC (Duke and UNC speakers at each session) and San Diego. The webcast had almost as many attendees in one day as we previously had in one year. The model takes the "best of AWARE" with Ken presenting the opening module and 4 patient speakers each telling about their experiences as participants in clinical trials. We packaged the tools so anyone could deliver AWARE locally. We provided every site with all the educational tools they needed and with a handbook of best practices and 10 suggestions/week on how to make their program successful. We encouraged the sites to supplement what we provided to them with local speakers. In this pilot offering of the AWARE webcast, there were a lot of Midwest sites, but we can reach every corner, and even small communities, with this model. The pilot was held at a variety of sites including a library, church, YMCA and winery. West Virginia University held AWARE at 6 sites using their grant process with an RFP that required them to use the webcast. In addition, one CTSA embraced the program.

Board of Advisors' presentations on 2010 contributions:

- **AWARE Support:** Linda Strause commented on AWARE-Clinical Research Education Day, specifically about AWARE San Diego (her hometown) and her pride in bringing the program to the West coast. Linda reported that the November 13th program was a success especially because of the broad involvement of the community – including UCSD, Scripps, ACRP, SoCRA, Sharpe, an IRB, Leukemia Society, etc. There were 28 community partners, 150 participants, 7 speakers, 5 health screenings. All exhibitors were very positive and had good interactions with the community. The attendees were comprised of 73% public and the balance health professionals. Pre- and post-test measures showed significant increases in comprehension. In the program assessment, everything scored as "good" or "excellent." According to the attendees, their main reasoning for not being in a trial was that they had never been asked. 94% answered that AWARE addressed their concerns. 70% reported that they were very likely to tell friends or family about what they learned. The patient speakers were amazing, especially the patient who talked about an artificial heart. All in all, Linda reported that AWARE-San Diego on November 13th was a great day.
-

CISCRP Board of Advisors Meeting

Diane pointed out how important Linda was in making this program come to fruition. Her efforts serve as an example of how a Board member plays a vital role in teaching a community about the clinical research process.

- **Professional Education:** **Jim Kremidas** explained his role in aligning CISCRP's mission with one of Quintiles' goals. In lieu of a big bash at the DIA, Quintiles corporate communications was interested in funding the "Voice of the Patient" special event at the DIA with John Crowley. This event provided good visibility for Quintiles; the DIA did a fine job promoting the event resulting in about 600 attendees. Diane thanked Jim for his novel approach to finding funding for a CISCRP program and Ken mentioned that since then, CISCRP has conducted Fabry Disease patient education as a webinar for Amicus Therapeutics.
- **Sales Tools:** **Diana Anderson** talked about her role in supporting CISCRP in 2010 with the development of a much-needed catalog that professionally positioned CISCRP, our mission and our educational tools. The CISCRP Catalog of Programs and Resources was produced in two formats for online and print; 1000 copies were printed pro bono and there will be a 2nd printing of 500. Diana explained that her approach is to call upon her print shops to donate. Diana also described another way she is planning to support CISCRP in 2011 with an exhibit booth. Her plan is that her company will handle design pro bono and ask vendors to donate or to provide at cost the 8 x 10 skins and screen and podium. The lesson learned from Diana is that your commitment can be in the form of time and not money; Diana finds people in her circle and explains what CISCRP does so that others will give.
- **Fundraising:** **Christine Pierre** talked about her most recent Site Solutions Summit and her approach to fundraising. Using slides about poor recruitment and an explanation of what CISCRP does, Christine just asked: What other industry has a nonprofit advocating on their behalf? Then she requested their contributions. In the first year of using this approach, Christine raised \$5000 for CISCRP; this year RxTrials matched the donations dollar for dollar and the total amount of the contribution was over \$14,000. CISCRP created a video for all the Site Solutions Summit contributors to put on their websites. Lani commented that it makes a difference doing fundraising in person and she asked where else this could be done, suggesting chapter meetings and lots of professional conferences. She noted that Christine's passion for our nonprofit made it possible, and Lani asked if anyone else could express a similar message at other meetings.

New Initiatives for 2011:

Diane and Ken echoed the message that growth is the theme for the upcoming year with additions to CISCRP's programs/services portfolio, as described by the CISCRP staff:

- In 2011, there will be 2 live AWARE programs (Chicago and Northern California) and then the focus will be on the webcast model. The goal is to reach 100 sites in the US and Canada by taking AWARE to the people; i.e., deliver the program at a Senior Center or at a church that is already holding a meeting organized by their Health Ministry.
 - We will expand our service of post-trial communication with multiple sponsors, providing clinical trial results in lay language to their clinical study volunteers.
 - Medical Heroes ads will be refreshed (with pro bono support from Ogilvy HealthWorld), not with actors but with real patients. Ogilvy will also help us in building momentum with viral petitions involving Medical Heroes in a "Just Say Thanks" campaign and a build-up of public/patient membership culminating in *Medical Heroes Appreciation Week*.
 - With continued funding from Lilly, we will continue to learn about the feasibility of outreach through pharmacists. We will survey pharmacists in 2011 to identify issues and impediments to fulfilling the
-

CISCRP Board of Advisors Meeting

public's interest in receiving clinical trial information from their pharmacist. We will also look to pilot a program where pharmacists provide education to their customers.

- We will build on the success of the "Voice of the Patient" with more patients telling their stories (comparable to the presentation at the recent NHLBI conference).

