Facebook As A CRO: Social Networks Become Factor In Clinical Trial Designs

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Drug companies soon may have to account for the effects of patients' social networking when designing studies, a **Pfizer** official said.

Craig Lipset, Pfizer senior director in clinical research, said patients are using chat rooms and forums directed at specific diseases, in some cases talking about the clinical trials in which they are participating and their experiences with the study drugs.

The online talk could threaten a trial's blinding and randomization, especially as patients are more able to interact with other trial participants, he noted.

In many cases, study subjects don't view a trial as an investment in the advancement of science. They consider it a last resort for treatment, he said June 7 during the National Library of Medicine's Clinical Trials Conference.

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Lipset said social media should not be the end of the randomized clinical trial, but he said designs will have to reflect the change in subject habits.

"We're not going to be able to ask our patients participating in trials to not socialize and not communicate, in particular, when we're looking at social media ... for its potential to recruit patients into trials," he said.

The Best Uses Of Real-World Data

Just as one of Pfizer's officials is raising concerns about how to deal with the Internet's effect on a clinical trial, the company announced it is beginning a trial that will be managed entirely through the Internet. Patients will be recruited via the Internet for a *Detrol LA* (tolterodine tartrate) trial in overactive bladder and report results to investigators using online tools.

The trial is intended to determine whether the method can produce results similar to a completed conventional Phase IV trial in the same drug (*"Can Pfizer's 'Virtual Trial' Change The Game, Cut Development Costs?" "The Pink Sheet," June 13, 2011*).

The Web has become a powerful tool for patient groups not only as a support mechanism, but also to disseminate information about new therapies, including those in clinical trials. Patients also post their own observations about their disease state and responses to different drugs.

Lipset said groups contact Pfizer regularly asking if they would like the longitudinal patient data they have gathered. He said the company is just beginning to understand the best uses of that real-world data.

"We've finally, I think, matured to a place of ... making sure we understand the types of questions we would like to address that could really only be addressed with real world data," Lipset said. "And I think we're really at the very beginning of understanding the range of how to properly use that information to best inform how we're developing our medicines and how we're interpreting those results."

Drug sponsors now are beginning to partner with those patient groups to improve enrollment in their clinical trials.

PatientsLikeMe, a website dedicated to charting real world data from patients and matching them with clinical trials, will announce at the Drug Information Association Annual Meeting, scheduled June 19-23, that it will offer drug developers tiered access to website members that meet trial criteria.

The site is working with BBK Worldwide on the project, the companies said in a June 14 statement.

PatientsLikeMe also announced June 9 it had enhanced its member features to automatically match patients with clinical trials in which they could be eligible to participate. Investigators also will have similar capabilities to search for eligible patients.

Paul Wicks, PatientsLikeMe's director of research and development, said at the clinical trials conference patients also can opt out of potential trial matches generated by the site for several reasons, such as because they are not interested or already are enrolled.

"I think as we start analyzing that data we might find out some interesting things about specific trial sizes, specific trial designs, that hopefully will help us as a group try to understand what interests patients and maybe help advise people on how to make their trials more appealing," Wicks said.

Social Networking To Support Research

Drug developers now are looking at how to use that data for research, rather than prevent it from spoiling it. Lipset said drug companies need to start listening to the conversations taking place on social media sites and patient community chat rooms and become more comfortable monitoring them.

That information can help companies understand how best to interpret the data emerging from a trial, Lipset said.

"Real-world data, crowd-sourcing, patient communities, this is not the end of randomized clinical trials," he said. "These are important sources of information and insight that we need to leverage in how we're designing and planning our studies and looking at the feasibility of our inclusion criteria and looking at the value of the endpoints we're trialing."