LETTERS

BY KIM RIBBINK

TARGETED MEDIA Messaging

PATIENT RECRUITMENT MARKETING

Patient recruitment is widely considered to be the most costly and time-consuming aspect of clinical trials, and the need to improve the process is pressing. One key aspect to achieving this goal is the use of appropriate media as part of a marketing campaign to improve patient enrollment.

Considered by the pharmaceutical industry to be one of the biggest hold ups in the clinical-trial process, patient recruitment is a highly complex process and one that experts say often lacks direction and focus.

The need to improve planning and execution is mission critical. Finding more efficient marketing campaigns and new ways to attract patient populations will drive the time-saving push for most big drug manufacturers, according to a report from Cutting Edge Information titled, Accelerating Clinical Trials: Budgets, Patient Recruitment, and Productivity.

"Using media to drive patients to study sites can be extremely successful when companies purchase the right vehicle targeting the right patient demographic and then use the media to motivate the prospective patient to respond by using professional creative and a repetitive call to action," says Julie Ross, executive VP at Essential Group Inc.

By employing a variety of appropriate strategies, tools, and media approaches to the recruitment process, clinical studies can be accelerated. But as experts in the field point out, the emphasis must be on appropriate.

"Sponsors, as well as sites, often fall back on advertising versus other media outreach tactics because it is known and comfortable," says Mindy Warner, senior VP at Fleishman-Hillard Clinical Trials Division. "But for many trials, advertising is not a sound approach because targeted strategies are required to influence small groups of patients. Advertising is not a wise spend when a narrow audience is being sought and the effort will result in high screen fail rates."

When evaluating the appropriate media, several factors need to be taken into consideration, including disease state, population, and geography. (See related chart on page 32.)

By understanding the demographics of a given disease, the sociodemographics of the people in that area, and their media habits, companies can gain insights into the types of media that will offer the best return on investment, says James Kremidas, manager of global enrollment optimization at Eli Lilly and Co.

"It's the same discipline that traditional direct-to-consumer marketing uses: know where the patients are geographically, understand their media habits, and then target the media that they're more likely to observe or listen to," he says.

Joan F. Bachenheimer, founding principal at BBK Worldwide, says it makes sense to adapt the marketing principles of product, price, place, and promotion to the patient-recruitment setting.

"In clinical research, the product is the protocol design, the price is the patient's benefit of participation, the place — countries/sites — is where the study is conducted, and pro-

JULIE ROSS
Essential Group

Knowing where to place media is driven primarily by using syndicated market-research tools.

26 February 2007 PharmaVOICE

Delivering Value on Patient Recruitment

With respect to your article on patient recruitment in February's issue, "Patient Recruitment Marketing," I believe sponsors are not getting the return on investment on their expenditures from patient recruitment organizations (PROs) for a few reasons not mentioned. It has been my experience that many PROs fail to deliver added value because of the sponsors' internal processes, organizational structures, and timing of events.

For example, the processes of identification and selection of sites are done far in advance of having completed protocols and site budgets, and are done by study project teams that are usually not responsible for screening and selecting patient recruitment organizations.

The timely release of completed protocols and site budgets needs to occur well in advance of the selection of sites so the physician investigators/sites can do their due diligence as to their populations and/or their estimates as to profitability of a study since most sites are for-profit operations. If that were the case the value or nonvalue of a PRO could be better determined.

As CEO and founder of a multitherapeutic network of 391 independent sites throughout the United States for the past 10 years, I believe it's in the best interest of sponsors to assist sites in any way possible to be successful before site initiation. Sites should be prepared to rapidly enroll and retain within the timelines from date of receipt of drug.

Site Value

I think most agree the PI/coordinator/patient relationship is key to enrollment and most importantly retention.Therefore PROs should be viewed in the context of their value added to each site that agrees to participate in a study as opposed to being viewed as an added value to the study as insurance against pre-established sponsor timelines.

— Dan Ulrey, Midwest Clinical Support Inc.

While I agree there is a shortage of patients in many clinical indications, there is a "critical" shortage of experienced profitable, GCP-compliant, U.S.-based investigators and study coordinators.

I think most agree the physician investigator/coordinator/patient relationship is key to patient enrollment and most importantly retention. Therefore PROs should be viewed in the context of their added value to each site that agrees to participate in a study as opposed to being viewed as a value add to the study as insurance against pre-established sponsor timelines.

PROs working with each site in advance of initiation to develop an individualized plan that each site agrees to would be a big step in the formation of proactive partnerships and possibly could be a criteria for the selection of the PRO as an alternative source.

I believe the time has passed when clinical R&D was viewed and organized primarily as a cost of doing business instead of more appropriately as the key asset on a sponsor's balance sheet — an asset that is 100% controlled by the success or failure of independent sites to enroll and retain patients and deliver data. Sites and patients should be viewed as partners and not commodities with respect to clinical studies.

In conclusion, I suggest we bury the term "trials" once and for all and call them what they are from the viewpoint of a prospective patient — studies.

Not being a judge or a prosecutor I try to avoid participating in any kind of trial. I think most prospective patients would also agree.

Keep up the good work.

Daniel M. Ulrey
President and CEO
Midwest Clinical Support Inc.

Prediction for Personalized Medicine

As our industry develops more targeted therapies through pharmacogenomics, healthcare public relations will play a pivotal role in educating the public about personalized medicine. (See "The Age of Personalized Medicine," February 2007 issue of PharmaVOICE.)

The lay attitude is crucial to successful implementation of personalized medicine, which has the potential to deliver significantly more effective diagnosis, therapeutics, and patient care.

Clients will rely on public-relations programs to arm consumers with the facts about pharmacogenomics research, science, and ethical issues, through comprehensive and balanced media coverage and customized educational initiatives.

Ilyssa Levins
President
HCIL Consulting

Pardon us ...

In the February 2007 issue of PharmaVOICE, we inadvertently provided an inaccurate company description of Model N Inc. in the article "Looking Ahead: The Deficit Reduction Act."

Model N, which is based in Redwood Shores, Calif., is a provider of revenue management solutions.

To learn more about the company, please visit modeln.com.

PharmaVOICE apologizes for the error and any confusion it may have caused.