

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.

onsidered 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



JULIE ROSS Essential Group

Knowing where to place media is driven primarily by using syndicated

market-research tools.

at BBK Worldwide, says it makes sense to adapt the marketing principles of product, price, place, and promotion to the patientrecruitment 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-





When a broad audience strategy does make sense, the use of local media relations can be a strong alternative because stories appearing in local media carry a great deal more credibility and are less expensive than advertising.

motion consists of the messages and materials used for outreach to study audiences," she says. "We also add a fifth 'P' to represent the patient. Patient needs must be the focus of every aspect of the critical planning phase."

UNCOVERING THE BOTTLENECKS

The statistics on patient recruitment in the United States are sobering, and they emphasize the need for improvement.

Among the common mistakes made in the recruitment process cited by experts are a failure to consider the patient population or the physician-patient relationship in designing a campaign; the site's capacity; poorly considered choice of media and recruitment tactics; and failure to forecast, report, and redeploy, as needed.

"The patient-recruitment tactics often



JAMES KREMIDAS
Eli Lilly

Patient recruitment should use the same disciplines that traditional DTC 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.

employed are typically untargeted and result in a very high attrition of potential candidates," says Malcolm Bohm, president of Trialytics Inc. "The media employed can range from simple newspaper advertisements to sophisticated campaigns using the broadcast media and/or the Internet. Unfortunately, throughout the process potential candidates are lost at every stage of evaluation because of ineligibility, which remains undetermined until the candidate is actively screened."

Additionally, overlooking the patient's own hopes and expectations is a common mis-

take, says Elizabeth Moench, president, CEO, and founder of MediciGroup Inc.

"The advertising message must be honed to target the patient population and convey the benefits for the patient," she says.

Any good marketing campaign should get across the

message of what it means to be in a clinical trial.

"There's a sense that people who participate in clinical trials are thought of as guinea pigs, and who wants to be a guinea pig," Mr. Kremidas asks. "We're working with an organization called CISCRP to help communicate to the general public that people who participate in trials are really heroes for society. That's an important point that often gets missed."

While, according to Ms. Bachenheimer, the most effective patient recruitment is created using the principles of marketing, most often study teams do not have access to the data necessary to make real-time decisions and/or redeploy as needed.

"And in the age of the Internet, new marketing methods are constantly evolving; however, even sponsors who have begun to use Web marketing may believe that they are not getting adequate results," she says.

These miscues are highly costly. According to Cutting Edge Information, each additional day a drug spends in clinical development could cost companies \$600,000 in lost revenue for a small or niche drug and upward of \$8 million for a blockbuster.

One approach Lilly has taken is to look for synergies around disease states.

"We might have three different molecules for diabetes running in three different studies, using different ads and buying different media," Mr. Kremidas says. "Let's assume each study

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has \$500,000 for its advertising campaign — that's \$1.5 million. We've decided to not advertise each individual trial, but to advertise about diabetes trials and when people call we can triage them through our call center or Website to the most appropriate study. This might mean spending \$1 million instead of \$1.5 million."

Mr. Bohm says the use of healthcare transactional data — clinic diagnostic data and pharmacy prescription data — is emerging as a valuable way to identify the right patients and their physicians on a per protocol basis, proactively.

Thomson CenterWatch

PATIENT RECRUITMENT marketing

A study BBK conducted in 2004, International Will &Why Survey, found that out of 5,000 respondents, 71% reported having read,

seen, or heard an advertisement about a clinical study.

"Eighteen percent of respondents said they

had taken an action as a result of reading, seeing, or hearing an advertisement or information on a clinical study," Ms. Bachenheimer says.

Sound Bites from the Field

THE INTERNET AND OTHER ALTERNATIVE COMMUNICATIONS METHODS HAVE ADDED NEW DIMENSIONS TO PATIENT RECRUITMENT. PHARMAVOICE ASKED EXPERTS IN THE FIELD: WHERE DO YOU SEE PATIENT RECRUITMENT EVOLVING IN TERMS OF METHODS IN THE COMING YEARS?



SILVIO ALADJEM, M.D., FACOG, is CEO and Medical Director of Midwest Consultants for Clinical Trials LLC, a clinical trial company that specializes in

the management, execution, and analysis of clinical trials ranging from small, focused studies to complex, multinational projects. For more information, visit midwestcct.com.

There is a need for a change in recruitment thinking beyond adopting new technologies. The resulting gains from new technologies are counterbalanced by the loss of patients because old methods are not used any more. The net gain is insignificant.

Our recruitment will improve only to the extent that we target new pools of patients. By recruiting mostly from large urban areas, other large pools of potential patients have been ignored. We must target nonmetropolitan and rural areas that will open new markets for patients and physician recruitment.

The greatest difficulty is for the pharma industry, including large CROs, to recognize the need for a culture change.



DIANA L. ANDERSON, PH.D., is President, CEO, and Founder of D. Anderson & Company (DAC), Dallas, a leader in the arena of patient

recruitment and retention offering clients innovative, cost-effective, site-focused, and results-oriented subject recruitment programs. For more information, visit dandersoncompany.com.

We've already witnessed tremendous growth in terms of people responding to

clinical-trial opportunities via the Internet, however, we've only scratched the surface as this powerful communications tool continues to improve as new technology is introduced.

Clinical-research studies are being conducted more and more on a global scale in countries with large and diverse patient population groups.

This trend will increase in the coming years so understanding the rules, regulations, and customs in every country where studies are taking place will be extremely important.

As the industry becomes adept at understanding these issues, developing more sophisticated, targeted messaging will be required to attract the necessary subjects.

With more people being connected every day to the Internet and as search engine optimization continues to evolve there will be newer and faster ways to gather, process, and prioritize information in any language. This will have a positive impact on generating awareness and qualifying people for studies. Thus, the Internet will remain a vital resource for patient-recruitment initiatives and may very well be the primary driver for these endeavors well into the future.



DAVID FOX is CEO and President of Praxis, Brentwood, Tenn., a clinical services provider specializing in patient recruitment. For more information, visit gopraxis.com.

The Internet will continue to evolve as an important source for medical information.

Geo-targeted searches, Web portals, and e-newsletters are among the tactics used to reach this audience. Digital online technology also plays an important role for real-time tracking of study enrollment, as well as an information tool for potential patients.

Individuals can go to a designated study

Website and fill out a prequalifying questionnaire to determine if they might be a good candidate for the study. This helps save time and money for both the pharmaceutical company and sites because they will get only prequalified patients.

One of the key advantages of the Web is its 24/7 availability, so feedback is immediate. Media habits today are extremely fragmented. That being said technology, while an important piece of the equation, is only a portion of the complex issues of patient recruitment.



J.TOBIN GEATZ is CEO of Inclinix, Wilmington, N.C., an enrollment CRO offering customized trial recruitment using recruitment experts

complemented with the power of technology to produce successful and timely study completion. For more information, visit inclinix.com.

New media will continue to complement traditional media in patient recruitment. Effective patient recruitment involves reaching out to exact patient populations and requires an advertising medium suited for localization. Traditional media remain the most effective means for targeting audiences demographically and geographically, while the Internet and new media are broader-based and provide a great communications channel for creating intimacy with patients identified through traditional media.

Moving forward, the solution will extend beyond this combination of new and old media and involve providing physicians with tools to better identify the most ideal patients — those already inside their practices.



JOAN BACHENHEIMER BBK Worldwide

Ideally, patient recruitment should be considered even before a protocol is designed. A best practice is to include members of the study team and/or patient recruitment consultants concerned with and experienced in patient recruitment during protocol design and approval.

"Almost 30% of respondents reported that the advertisements or information they had been exposed to were helpful or educational."

SELECTING THE RIGHT MEDIA

The choice of media tools and the timing are crucial to success. Both traditional media-based advertising and Web-based recruitment are an important part of the mix, but as experts point out, careful thought must be given to the type of study being undertaken.

Applying a one-size-fits-all approach rather than allowing sites to employ their local knowledge will cause pain and angst for a site, says Art Schoenstadt, M.D., president of Clinaero.

"Take an obesity study, for example, where there are obviously a fair number of people who fit the therapeutic area, and in such cases any marketing at all will only inundate the study with inquiries," Dr. Schoenstadt says.

And while recruiting for a disease such as



MALCOLM BOHM Trialytics

Progress has been made developing more compelling messaging through media that appeal directly to patients and their physicians.

diabetes lends itself to mass media, such an approach would not be appropriate for a patient in an acute state, experts say.

"The types of diseases for which a patient can self-report are the ones where mass media tends to work the best," Mr. Kremidas says. "Obviously, if someone has been admitted to the emergency room with a heart attack, mass media is a horrible choice, because it wouldn't be right to have an ad that says 'if you have a heart attack think about being in this study."

It's about knowing the target audience and employing the appropriate tools, such as coor-

dinating strong referral processes and networks within and outside the investigator site, and providing sites with recruitment tools to promote the study.

"In some cases, tools that help the investigator educate and promote the study to their colleagues would be appropriate," Ms. Ross says.

According to Gernot Cremer, director of clinical research services Europe for Medifacts International, use of media, particularly the Internet, is growing, especially when it comes to recruiting for trials that involve rare and fatal diseases

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"Diseases such as cancer or pulmonary hypertension have Internet forums and patient communities that alert members to new hopes with regard to substances coming into clinical trials and which clinical centers participate," Mr. Cremer says.

The population being targeted is also a consideration, and any campaign must consider carefully cultural and language differences in the recruitment message and be sensitive to differences in attitudes and traditions around healthcare.

"Hispanic patients typically rely on the pharmacist more than a physician and involve all family members in healthcare decisions," Mr. Bohm says. "Language is also a barrier that must be carefully considered to ensure messaging crosses cultures. African-Americans are skeptical about clinical trials and are often deeply suspicious of the proposed merits of clinical trials. Achieving community advocacy in this group is key. Adapting recruitment tactics to fit the subcultures and geographies in the United States is critical to achieve uniform recruitment success."

According to Cutting Edge Information, the use of mass-media recruitment ads for print, radio, and TV present many challenges. For example, regulations against "selling" a trial limit the messages designers can use to target small populations through media outlets that reach thousands, thus making the effort less cost effective per enrollee.

The best approach is to use a campaign to drive potential patients to channels that provide more extensive information.

"A common mistake sponsors make is focusing on tactics and forsaking strategy," Ms. Warner says. "For example, as interactive recruitment strategies are increasingly employed, it is not uncommon for sponsors to build a study Website but then not deploy enough online and offline tactics to drive target audiences to the site."

While some say investigators are often the best judge of the media and communications tools that will work best in a given area, others disagree.

Ms. Ross notes that allowing sites to develop their own advertising messages is a mistake since they generally do not have the marketing savvy required to maximize the local recruitment advertising investment.

The onus is on the sponsor to ensure investigators have recruitment kits, such as text for print ads and fliers, copy for local radio and TV ads, and templates for the overall design and look of the recruitment drive.

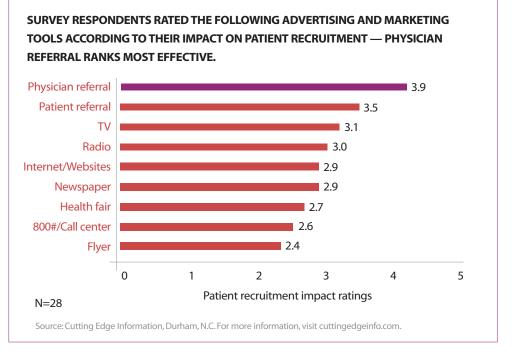
Web-based recruiting offers access to an often untapped audience that is engaged in seeking information about a disease.

UNCOVERING THE ROI IN MEDIA FOR PATIENT RECRUITMENT

- Be open to media options. There is a misconception that TV is more costly than newspaper and radio. When trying to recruit large patient populations, TV is actually less expensive because of its mass reach.
- Invest in professional creative. Effective, impactful advertisements maximize response and therefore ROI on advertising dollars spent.
- Make sure that the recruitment firm is closely monitoring and measuring the media response and moves out of markets that are proving more costly than originally forecasted and into markets that are more cost-efficient.
- O Sponsors should evaluate the ROI for a recruitment program compared with the cost of extending enrollment, adding sites, reducing patient randomization targets, or considering the benefit of shortening enrollment.
- O If there are multiple studies for the same indication running at the same time, consider planning one recruitment program that will recruit patients for all studies, instead of multiple recruitment programs.
- Be open to allowing a recruitment vendor to use and place the advertising resources budgeted within the physician grant. The advantages are: maximizing the demographic reach; the cost for the media buy is at a better rate as vendors receive volume rates; a professional creative message with a high call to action is delivered; and funds can be amortized such that sites in expensive markets are supported equally to a less costly smaller market.

Source: Julie Ross, Executive VP, Essential Group Inc., Gurnee, III. For more information, visit essential groupinc.com.

PATIENT RECRUITMENT ADVERTISING AND MARKETING TOOLS



"We are constantly researching new Webbased tools that may make it possible to revolutionize search engine optimization algorithms that lead patients who are doing online searches — for clinical studies specifically, or about their condition in general — directly to relevant, local study Web pages," Ms. Bachenheimer says.

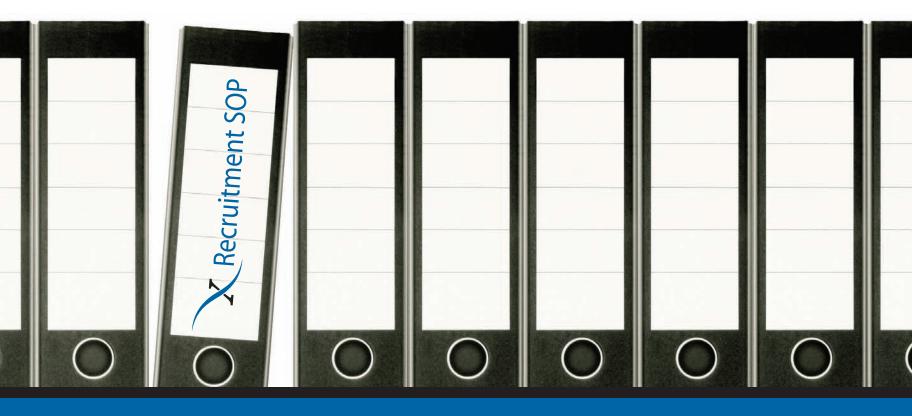
She says a benefit of such an approach is

that it offers patients educational information and an opportunity to consider joining a clinical study at the moment in time that they are seeking health information.

Additionally, Internet recruitment offers the ability to discuss the clinical trial in more detail and with greater freedom than traditional avenues.

Cutting Edge Information notes, for exam-

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FACTORS	CONSIDERATIONS	MEDIA DECISIONS
Disease state	Prevalence rate versus population	Targeted media to disease state versus general population
	Geographic prevalence	Example "Psoriasis magazine" versus mass media
	Healthcare setting	Cost-efficiency of media selected
Population	Age	Type of media: broad reach or niche, gender skew, psychographic profile
	Gender	Culturally targeted media
	Ethnicity/Language	Cost-efficiency
	Mobility	
	Cultural differences	
	Income	
Geography	Travel distance to sites	Media reach by zip code
	Weather conditions	Media waste because of geographic over-reach
	Metro versus rural markets	Regional versus national publications
		Overlapping media markets/dominant media market
Sites	Single site versus multisite markets	Media reach to benefit multiple versus single site
	Weekly capacity of sites to screen patients	Input on media selection by site based on historical performance
	Centrally managed advertising versus local	
	staff experience	
	(study coordinator, on site recruiter)	

Source: MediciGroup LLC, King of Prussia, Pa, For more information, visit medicigroup.com.

ple, that pharma companies can, on the Web, describe details of the trial, such as the number of injections, and talk about the disease.

"Preparing a video-based presentation for the Internet that goes into detail on the risks and benefits of a particular clinical study, as well as what responsibilities enrollees will have, enables those interested in a study to gain a good understanding of what the study is about before they talk to the site," Dr. Schoenstadt says.

HOW AND WHEN

The Cutting Edge Information report notes that successful recruitment campaigns begin in the planning stages and employ the right combination of tools to meet patient requirements mandated by the study protocols.

"It's important to think about the patient recruitment marketing drive from the beginning of the development of the clinical plan," Mr. Kremidas says. "At Lilly, when the clinical plan is developed a decision is being made whether we should take it from Phase II into Phase III, and at that point funds are assigned to that molecule. If we don't have that plan going from Phase II to Phase III, and we don't tell the team how much money they're going

to need for enrollment, then they don't have the budget downstream."

Some companies wait until milestones are missed before beginning a recruitment plan, Ms. Moench says, while others are more proac-

'While proactive recruitment efforts require up-front investment, reactive cam-

paigns can result in higher costs because of already sunk costs resulting from delays," she says. "The disciplines of risk assessment - time versus money - are critical drivers of the recruitment process."

If the recruitment drive is to have maximum impact, both centralized and decentral-

ized recruiting must be employed, the Cutting Edge Information report says.

"Centralized recruitment advertising can create significant cost savings when advertising 'clout' is leveraged in markets with multiple sites," Ms. Moench says. "This generates savings that individual sites, placing advertising individually on their own, may not realize."

But centralized recruitment campaigns must be reinforced with appropriate content in local advertising channels.

"Large metropolitan markets can be great sources of patients for DTC campaigns because of the population concentration and the broad reach of many media vehicles," Ms. Ross says. "If the sites are on the outskirts of a large mar-

> ket, it is not cost-effective to run media that draws the entire population, many of whom will not travel the distance to the site. The advertising message should be localized, reaching fewer people."

Cutting Edge Information notes that decentralized patient recruitment often

begins during investigator meetings, where companies distribute ready-made recruitment kits containing IRB-approved messages, radio and TV copy, templates for letters to local physicians, and flyers for use in local advertising campaigns.

Mr. Bohm says it's important to include marketing and commercial perspectives in the



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PATIENT RECRUITMENT marketing

Phase I trials last, on average, 42% longer than initially expected; Phase II trials last 31% longer; and Phase III trials extend 30% beyond initial deadlines.

Cutting Edge Information

recruitment strategy.

"This means that the opposing forces of recruitment feasibility

and protocol complexity can be achieved synergistically while ensuring commercial and marketing stakeholders understand the emerging product target profile," he says.

Mr. Kremidas argues that the recruitment campaign should be conducted by the clinical-development team.

"Not to say that you can't borrow ideas from marketing in terms of how to approach the advertising campaign, but we like to keep a firewall between marketing and medical to avoid any potential for premarket promotion," he says.

Call centers, which help funnel patients referred by the mass-media campaigns, are commonly employed. Call centers also provide recruitment companies with important data, such as what drew patients to the clinical study, information that can be used to better plan for the next trial, the Cutting Edge Information report states.

"Without data, it's not possible to determine for a particular patient group in a particular study what

works — radio, television, newspapers, or interactive — and that's the challenge," Dr. Schoenstadt says.

According to Ms. Moench, one valuable approach to overcome this obstacle is to conduct real-time monitoring of site performance in terms of converting advertising efforts into randomized patients.

"Instituting a patient-recruitment plan that recognizes the importance of site performance in ongoing advertising investment — namely directing advertising to performing sites that are achieving recruitment targets and minimizing or eliminating advertising for nonproductive sites — can minimize waste and maximize productivity for every dollar invested," she says. •

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.



ELIZABETH MOENCHMediciGroup

Simply stated, a well-planned, well-targeted, and well-executed advertising campaign can result in maximum ROI for every advertising dollar invested.

Experts on this topic

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