

Patient Recruitment Companies Band Together

- A group of patient recruitment companies plan to form a trade organization next spring to raise awareness about how patient recruitment programs can be strategic investments that help drug sponsors bring new drugs to market more quickly. They also want to address issues such as how the trend toward global clinical trials is affecting their niche industry. Not all of the major players are on board with this effort.
- As demand for patient recruitment services has increased in recent years, the sector has seen rapid growth in the number of companies offering recruitment services. The patient recruitment organization space includes about a half dozen established, full-service patient recruitment and retention companies and an increasing number of smaller niche companies. Global CROs, such as Kendle, Quintiles and Parexel, also have established patient recruitment divisions as part of their full-service offerings.

A group of seven companies involved in patient recruitment for clinical trials, which range from small public relations firms to full-service patient recruitment and retention providers, has plans to form a professional trade organization by next spring as a way to help strengthen their niche industry.

The 12-member committee, called the Patient Recruitment Organization (PRO) Steering Committee, aims to raise awareness about how patient recruitment programs can be strategic investments that can help drug sponsors bring new drugs to market more quickly and to address issues in the industry, such as the trend toward global clinical trials.

“It is exciting that competitors can come together in an effort to uplift the industry. By uniting in this way and jointly participating in education and standardization, we can influence everything from public perception to public policy,” said Lance Nickens, president of Texas-based The Patient Recruitment Agency (TPRA), one of the companies participating in the steering committee.

In addition to TPRA, companies involved so far are D. Anderson and Company; Healthcare Communications Group; Patient interaction; Fleishman-Hillard’s Clinical Trials Division; RxTrials, and On the Scene Productions. However, three of the leading full-service patient recruitment companies—BBK Worldwide, MediciGlobal and MMG—were noticeably absent from the PRO Steering Committee’s April kickoff event in Philadelphia.

Yet those involved in the steering committee believe the group has the potential for making the patient recruitment industry stronger. “By conveying to the industry that here are some of the issues and trends that collectively we all face and that they do impact the ability of

sponsors to do efficient recruitment, we want to increase sponsor understandings of those types of issues for their benefit,” said PRO Steering Committee member John D. McAnulty, senior vice president and partner of Fleishman-Hillard’s Clinical Trials Division.

Steering Committee Formed

Diana Anderson, Ph.D., president and CEO of D. Anderson and Company (DAC), who came up with the concept for the group, said the PRO Steering Committee was established to address some of the issues around the growing patient recruitment market.

“We have been talking about forming such a group for a couple of years now. As the patient recruitment and retention niche has grown, particularly over the last five years in the pharmaceutical industry, I have felt that we need to be working toward some formal organization that will allow us to share the knowledge that we have not only as competitors, but as collaborators in order to continue to help to grow and professionalize our field,” said Anderson, who chairs the steering committee.

According to a 2003 IBM Institute for Business Value report, one of the rare surveys to put a number on the patient recruitment market, some 27% of drug development costs are spent on patient recruitment, which equals \$5.9 billion annually around the world.

While study sponsors traditionally have relied on clinical research sites to recruit subjects for their studies, Fleishman-Hillard’s McAnulty said that recent research shows that sites recruit an average of 75% of the patients, which leaves a 25% gap in the number of subjects needed to enroll a study. “That is where companies like ours come in. If you plan for that eventual-

ity upfront, you are more likely to be able to fill that gap,” McAnulty said.

The difficulty in recruiting patients remains a major reason that clinical trials run over budget and miss deadlines. According to a 2007 CenterWatch survey, enrollment problems delay more than 70% of clinical trials from one to six months. To eliminate delays in clinical trials, and reduce time to market, drug sponsors increasingly turn to patient recruitment providers to both rescue trials that have failed to meet enrollment objectives and for strategic advice early in the drug development process.

As demand for patient recruitment services has increased in recent years,

...the sector has seen rapid growth in the number of companies offering recruitment services.

the sector has seen rapid growth in the number of companies offering recruitment services. The patient recruitment organization space includes about six established, full-service patient recruitment and retention companies and an increasing number of smaller niche companies. Many of these smaller companies are dedicated to a single process, such as providing patient databases, call center activities or appointment reminder assistance.

Many global CROs, including Kendle, Quintiles and Parexel, have established patient recruitment divisions as part of their full-service offerings; some CROs also train their clinical research associates to support the subject recruitment process. One of the PRO Steering Committee’s goals involves an assessment of the various stakeholders in the patient recruitment space.

“We are seeing niche patient recruitment providers growing every day. There are still comprehensive providers, but there are also many new areas of opportunities. How do the CROs fit into the market? So, the trend in terms of identifying the shareholders was another thing we discussed,” Anderson said.

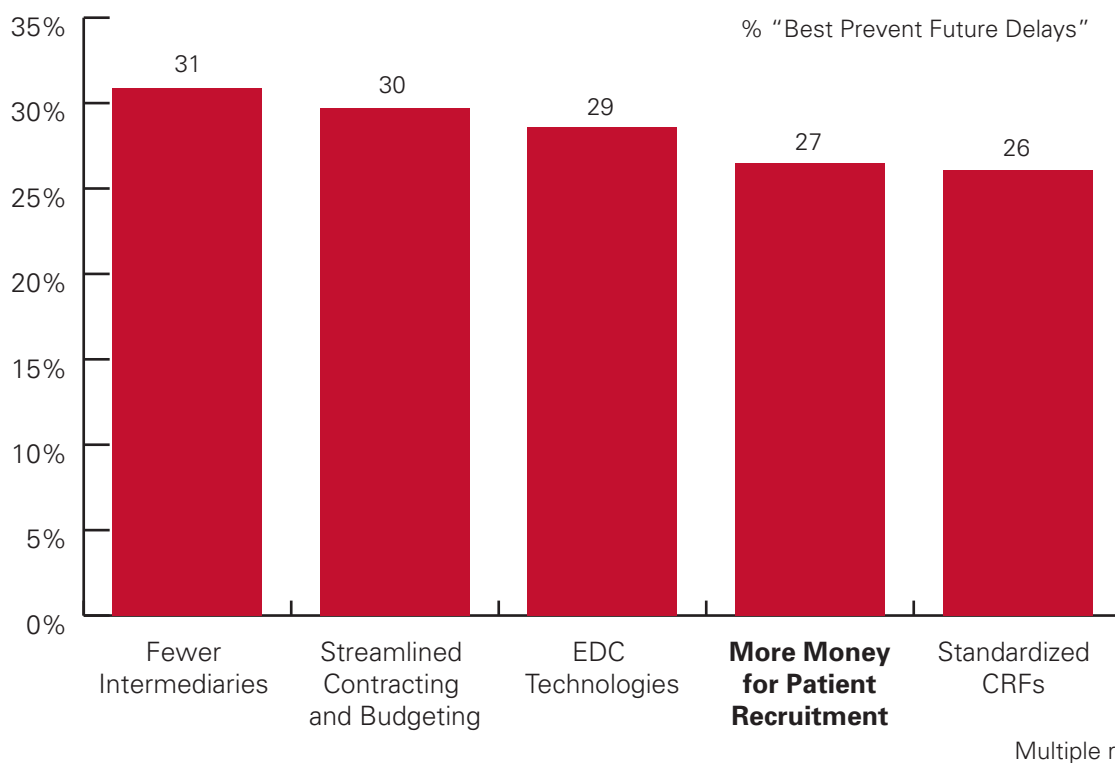
PRO Steering Committee member Frank Kilpatrick, president of Healthcare Communications Group, believes the organization is a “timely initiative” given the evolution of patient recruitment in recent years.

“It’s an idea whose time has come,” Kilpatrick said. “There is a realization that after 10 or 15 years in this role, companies like ours and our other member companies are clearly a part of the subject enrollment equation. Increasingly, we are part of budgets at some pharmaceutical companies, and, as such, there is the need to increasingly deliver our message and ensure that people who use our services have an understanding of what can be expected from an organization like ours, what the determinant of recruitment successes can be, what a professional group should look like.”

In April, DAC and TPRAs, which are both Texas-based companies, co-hosted a summit in Philadelphia for PRO Steering Committee members to discuss core issues affecting patient recruitment organizations and the need for greater collaboration among these companies. A total of 12 participants representing seven companies attended the event. In addition to DAC and TPRAs, other companies represented at the meeting were Healthcare Communications Group; Patient interaction; Fleishman-Hillard’s Clinical Trials Division; RxTrials, a network of independent clinical research sites; and On the Scene Productions, a video production company.

The group, which plans to add members in the future, has begun discussions about membership criteria for expanding the steering committee. Criteria might include the number of years

Factors That Could Best Prevent Future Delays



Source: CenterWatch Survey of Investigative Sites in the U.S., 2009 (n=950)

in the business, a minimum revenue level, or an assurance of proper licenses and insurance. “We hope to add representatives from all major patient recruitment providers both U.S. and international. We’ve had a number of people express interest in the group. We are kind of in a holding pattern until we decide how we want to proceed. Indeed, we hope to have lots of members eventually,” said DAC’s Anderson. “We hope to have a much larger summit meeting in a year. We probably will see this grow into a formal professional organization if not before next spring, at least at that point.”

Noticeably absent from the summit were key players in the patient recruitment space BBK Worldwide, MMG and MediciGlobal. “While we were invited to the April 16 meeting, we did not attend,” said Elizabeth Moench, president and CEO of MediciGlobal, one of the biggest players in the full-service patient recruitment space.

Moench said the purpose of the committee and what it hopes to achieve are unclear. “Typically, trade associations have a clear purpose, such as lobbying on key policy issues and a clear functional mandate within the industry. For competitive reasons, if you compare and look at the CRO organization [ACRO], there is an independent body that represents a clear policy purpose, so, too, does another industry organization—PhRMA—it serves as an independent group that brings all competing pharma companies together to establish common ground on specific policy issues. The involvement of independent bodies makes these groups transparent, unbiased and meaningful,” she said. “Here, in my opinion, the PRO Steering Committee is not an independent body. From the information I have been provided, it appears to have no clear sense of purpose, policy agenda or goals. Furthermore, after reading about the April 16 meeting, it appears that the PRO Steering Committee is more focused on first creating

a group, and then creating its purpose. I believe, to have sustaining power, a group forms because of an important emergent issue or issues.”

Although BBK Worldwide didn’t participate in the April summit, BBK Client and Prospective Services representative Elizabeth Gargill said the company understands the objectives of the PRO Steering Committee and applauds their mission.

“From early on, we built into the fabric of our company the sharing of information to advance the industry. This is reflected in our commitment to authoring byline articles and white papers, presenting at industry conferences, publishing a textbook on patient recruitment, spearheading Good Recruitment Practice, among other efforts. We feel that, given the constantly evolving constructs that guide patient recruitment, the sharing of information is important and, again, commend the efforts of the PRO,” she said.

Since the April summit, the steering committee has conducted monthly teleconferences and is moving forward with plans to develop a web site. The group also identified the following five “areas of interest” for advancing the patient recruitment and retention industry: Whether to form a professional trade organization; risk sharing; identifying industry trends; expanding globally; and improving how patient recruitment organizations work with stakeholders, including pharmaceutical and biotechnology companies, CROs and clinical trial sites.

“Right now, the committee has spent time formulating itself: Who are we and what do we want to achieve? I think we have gotten that far. Now we have to decide: Where do we go in the future? I think the goal would be to have a not-for-profit type of patient recruitment organization, where we would involve others in the industry who are involved with patient recruitment, including sponsors and CROs, and figure out how to

make that happen as a stand-alone member organization that is based upon educating anyone who is interested about patient recruitment. An organization focused solely on patient recruitment and retention doesn’t exist at this point,” said Fleishman-Hillard’s McAnulty.

Prevailing Market Trends

PRO Steering Committee members point to several market trends that underscore the need for greater collaboration and cooperation among patient recruitment organizations.

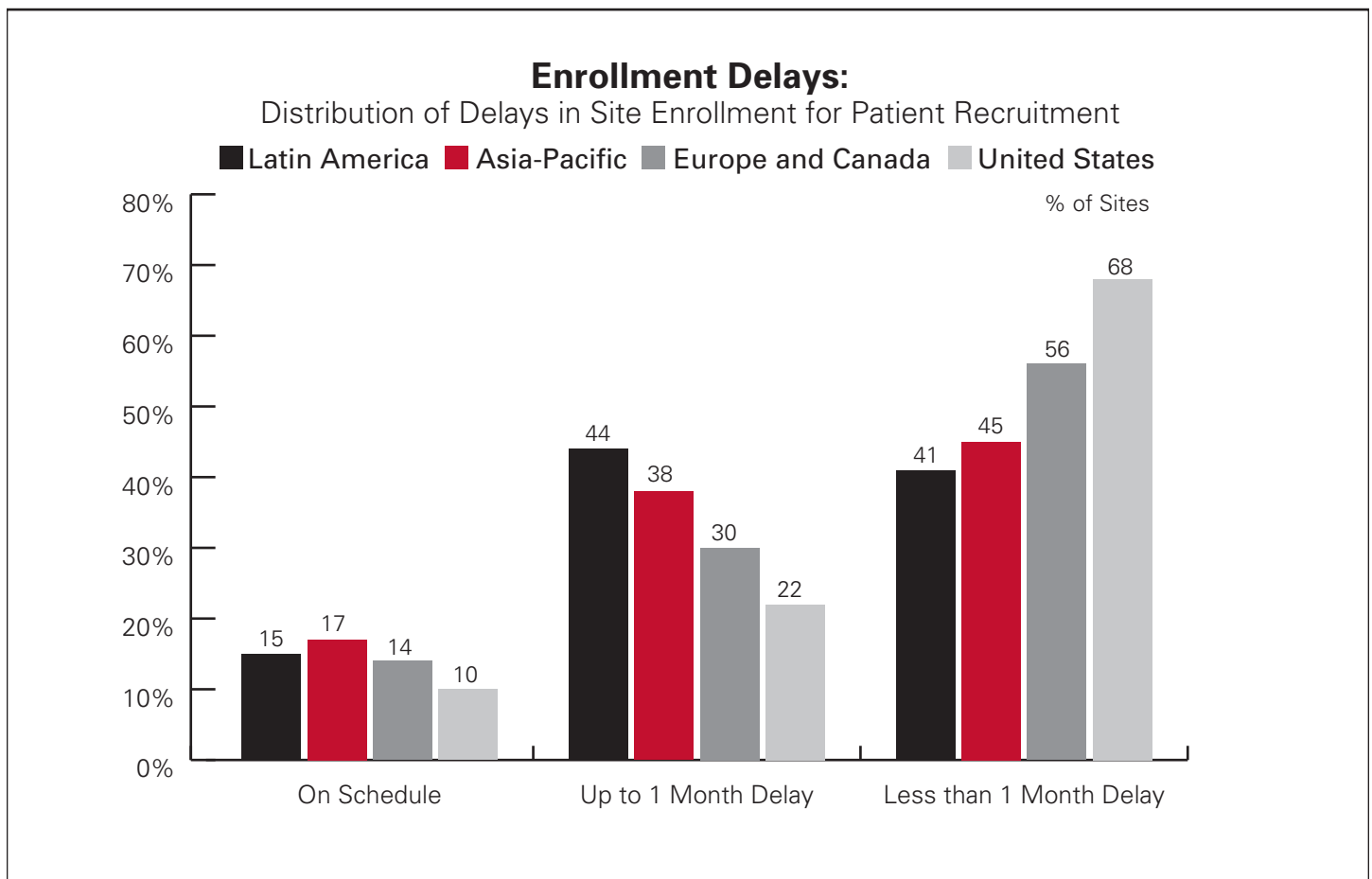
While the challenge of patient recruitment has been talked about in the field for years, there hasn’t been much improvement in patient recruitment processes. According to a 2009 CenterWatch survey of investigative sites, only 10% of clinical trials in the United

States are enrolled on time; in Europe and Canada, that number is 14%.

“There is the unresolved challenge that we, the members of the organization, need to work with sponsors to try to solve. It hasn’t been solved and isn’t a diminishing problem. If anything, with the increasing complexity of protocols, it’s an increasing problem,” said HCG’s Kilpatrick.

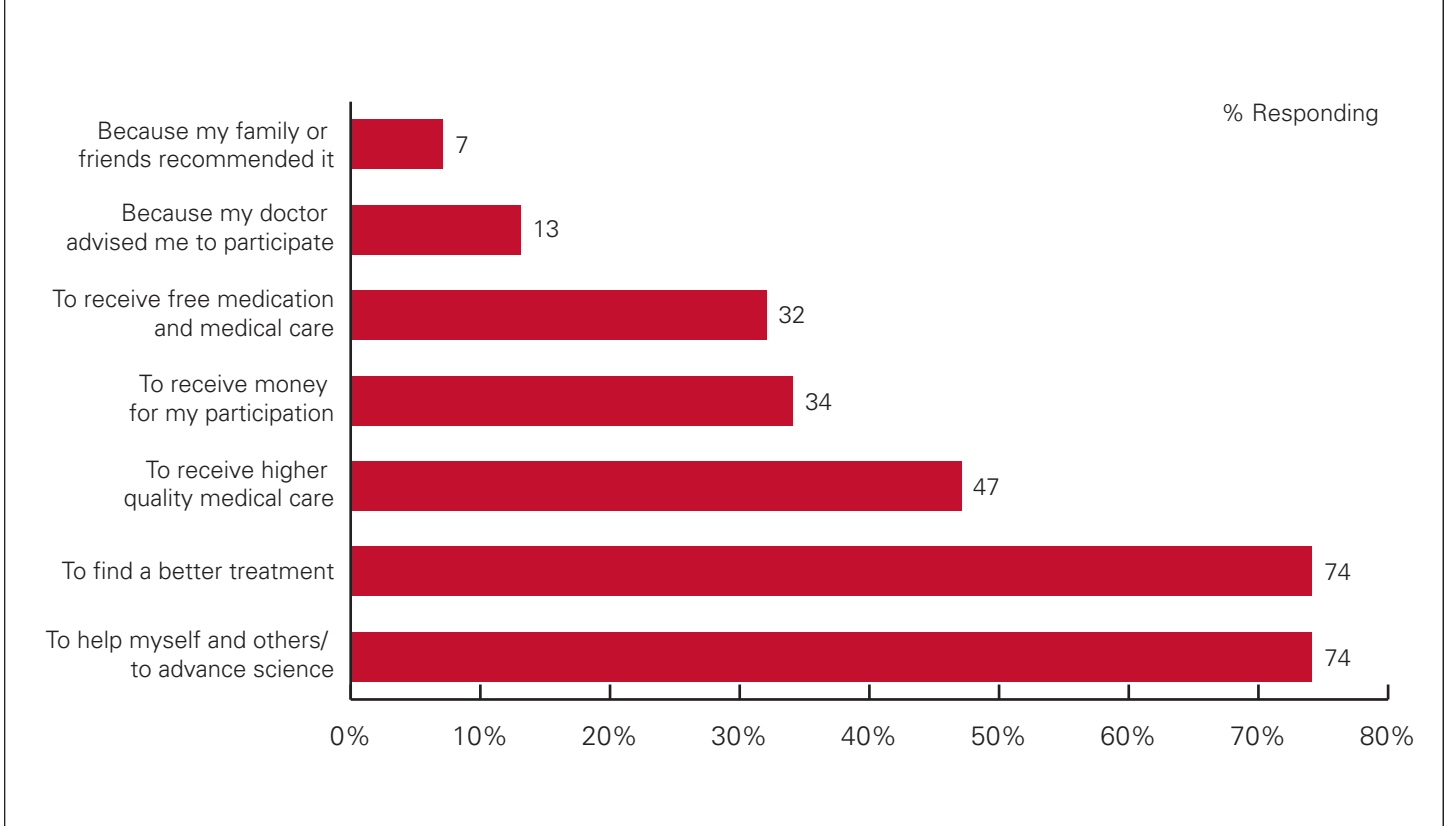
At the same time, drug sponsors increasingly look to overseas markets to expand the pool of available patients for clinical trials. Both DAC and HCG report more than half of their patient recruitment and retention projects are overseas. Global recruitment is one of the steering committee’s five “areas of interest” for advancing the patient recruitment industry.

“Certainly all of us are facing the issues of global trials. I think that is pretty consistent with the group,” said DAC’s Anderson. “That is a significant trend



Source: CenterWatch Surveys of U.S. (2009, n=950), Asian (2006, n=156), Latin American (2005, n=317), European and Canadian (2006, n=356) Investigative Sites

Factors Impacting Study Participation



Source: CenterWatch Patient Experience Survey, 2009 (n=670)

and opportunity that we are all dealing with: How do we best accomplish and deliver on a global scale?”

MediciGlobal’s Moench, however, is skeptical that global patient recruitment companies would want to share their strategies in such a highly competitive industry.

“Why would any company give away information about where they are going globally and what they are doing to a handful of competing companies?” she asked. “Within the industry, there are indeed some global policy issues that are surfacing, but these are already being examined by groups involved in social science, academia, policy and research. They are asking questions about whether informed consent can be objectively delivered in developing countries when the physician is seen as an authority figure or what industry should do when studies end and the medical system leaves patients stranded without medical care. This latter issue is being studied by an

Amsterdam-based group, the Wemos Foundation. They are examining some of the global ethical issues involving patients and clinical trials.”

■ Educating the Industry

While pharmaceutical companies already know clearly that difficulties in recruiting patients remain a major reason clinical trials run over budget and miss deadlines, Kilpatrick believes that, as an organized group, the PRO Steering Committee can explain the growing role of patient recruitment organizations to drug sponsors and the value these companies provide in improving clinical trial timelines. “There is knowing, and then there is knowing. For example, you might know what a CPA does, but if you are in a tax audit, you might not know what all the issues are that your CPA or your tax lawyer are going

to reference in terms of providing valuable counsel,” he said.

In particular, Kilpatrick said the PRO organization could help drug sponsors understand business benefits that patient recruitment companies can offer. “These programs are not inexpensive to undertake, but they are essential for many of these programs to get their developmental finish lines on a timely basis. If you spend \$1 million or \$10 million, you need to know, as a sponsor, that this is a good return on investment [ROI]. It’s not brand new. Good business people have been doing that for hundreds of years. But even some of the folks in the clinical development area are still learning how to measure metrics and ROI. That is something maybe we can help them with. It may, in fact, lead to something of a paradigm shift in really reviewing the overall cost of clinical trials because if what we do is reduce the enrollment timetable, we are going to reduce overall monitoring costs and we are going to

move some programs to their finish lines much more quickly.”

Fleishman-Hillard’s McAnulty believes the PRO committee can help establish best practices that can be shared with clients and potential clients to help them improve their own patient recruitment efforts.

“One example is the need for early planning for patient recruitment, for sponsoring companies to include patient recruitment as one of the core components of planning as they are starting up the study. From my experience in recent years, sponsors are getting better at this. But when we first started, we were involved in a lot of rescue missions; nobody had established any budget and they didn’t have resources to work with us. When you are doing a rescue mission, a lot of times you are not able to fully implement the strategies that need to be implemented because there is not time. You may think patient-facing activities should be occurring, but it’s

going to take two or three months to get the necessary IRB approvals in place. A lot of times, for a rescue mission, there is just not that amount of time,” McAnulty said. “We need to look at building a business imperative for patient recruitment that permeates the C-level suite at pharmaceutical and biotech companies and really having a commitment to patient recruitment initiatives at that level, based upon the economics of meeting versus not meeting patient recruitment goals.”

As they look toward the future, some PRO Steering Committee members want the group to help promote Good Clinical Practices and ethical processes throughout the world.

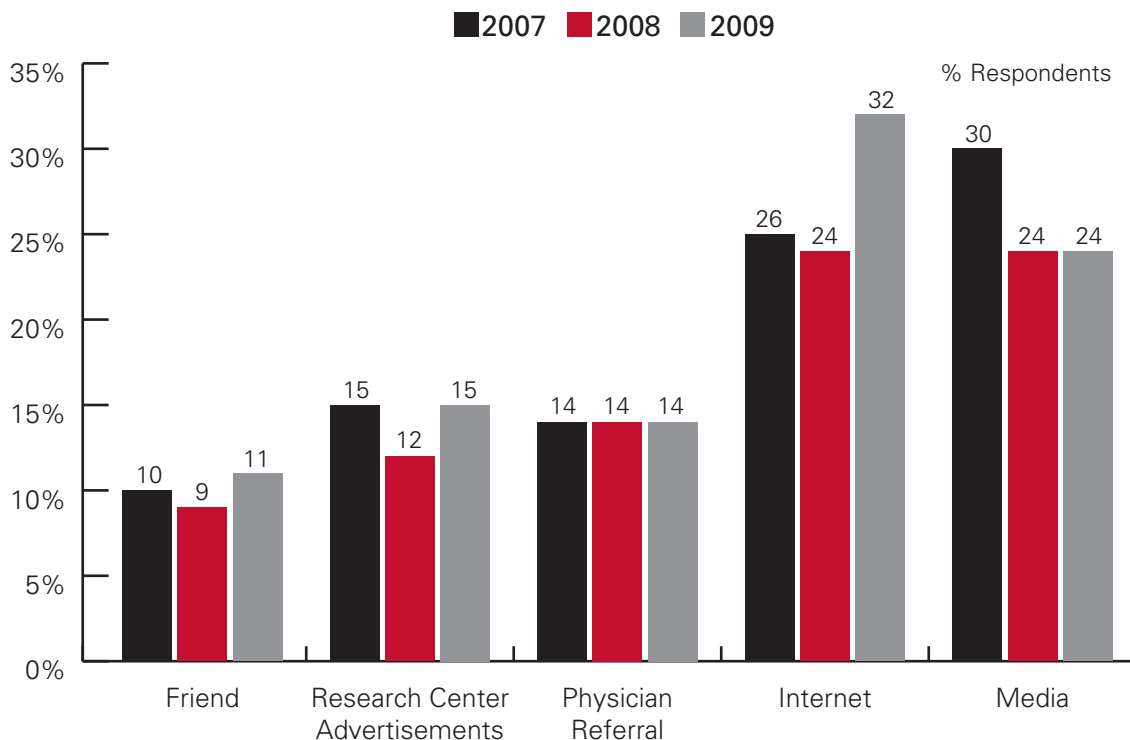
“In the steering committee phase, we will probably speak to the need for developing standards,” said HCG’s Kilpatrick. “After we have initiated some of the more logistical, tactical aspects, we would address those standards perhaps in White Papers and other types

of research initiatives. We are an organization in formation. I think that the thing that we are endeavoring to do is crawl before we try to walk.”



Karyn Korieth

How U.S. Patients Learn About Clinical Trials



Source: CenterWatch Patient Experience Survey, 2009 (n=670)