PATIENT RECRUITMENT

Clinical trials sponsors and medical communities need to make access to treatment easy for volunteers and provide physicians with transparent, clear information about investigational drugs.

This sector of the industry has become acclimated to an 80% failure rate when it comes to patient recruitment. This failure rate would not be tolerated in any other aspect of this or any other industry.

David Fox
Praxis

An emerging trend among pharmaceutical and biotechnology companies is more up-front planning and budgeting for patient recruitment. According to David Fox, president and CEO of Praxis, this is a trend that will continue in 2007.

"The industry is under increasing pressure to streamline the drug-development process while improving the yield of new drugs," Mr. Fox says. "The faster they can get to a go/no-go decision, the better. With the pressure to control costs and to speed up the process, more companies are looking at centralizing their recruitment dollars to maximize their investment. With patient recruitment taking up almost 50% of the cost/time of any given study, this is an obvious first place to look for new and better approaches."

As patient-recruitment centers of excellence inside major pharmaceutical and biotech companies continue to develop, Bonnie Brescia, founding principal of BBK Worldwide, says it's important to partner with customers to transfer knowledge, best practices, and processes through e-business solutions.

According to Denise Robinson, executive director of marketing at Inclinix Inc., unfortunately, most sponsors continue to wait until investigators fail to enroll enough patients and then implement rescue programs involving aggressive outreach components.

"Our goal must be to overcome the industry's wait-and-see tactics," she says. "In 2007, recruitment service providers will continue to be faced with the challenges of rescue recruitment programs."

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Denise Robinson
Inclinix

TECHNOLOGY AND TOOLS

The good news is that the tools are available to improve the enrollment process.

"By linking e-solution tools with other clinical operations technologies, there is tremendous opportunity to pair data with expertise to improve study planning, start-up, implementation, and postcompletion assessments," Ms. Brescia says. "Senior management will get the answers to questions historically met with 'we don't know.'"

According to Ms. Robinson, through technology, patient-recruitment providers have the greatest opportunity to influence volunteerism as a whole by identifying and educating clinical investigators and by continuing to promote clinical research in a medically ethical and positive manner.

Thought Leaders

BONNIE A. BRESCIA. Founding Principal, BBK Worldwide, Newton, Mass.; BBK Worldwide is an e-business solution company for the clinical R&D and product marketing segments of the pharmaceutical, biotechnology, and medical-device industries. For more information, visit bbkworldwide.com.

DAVID L. FOX. CEO and President, Praxis Communications Inc., Brentwood, Tenn.; Praxis provides the pharmaceutical and biotech industries with a wide range of services for patient recruitment and retention for clinical trials. For more information, visit gopraxis.com.

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Data safety monitoring boards (DSMBs) are a must to help improve the safety of volunteer research participants in our studies and improve a system in dire need of reform.

Darren McDaniel, Coast IRB

Despite the strong emotional component, both trial volunteers and referring physicians seem to enter the clinical-trial decision with a logic-based mindset.

Dr. Mary Jo Lamberti, Thomson CenterWatch

The adoption of technology, such as electronic or virtual information, i.e., virtual medical records, will be pivotal in the coming year, but it all hinges on the adoption of the medium and technologies by sponsors and investigators, Ms. Robinson says.

"Virtual medical records have the potential to change the investigator and patient-recruitment landscape, providing sponsors with the data needed to ensure that the best investigators are selected for trials and to ensure the appropriate patients can be found within the investigator's practice," she says. "To reach the intended patient audiences, clinical-service vendors need to continuously update the ways that information is delivered. Over the next year, companies that have experienced success recruiting investigators and patients solely using traditional methods may have to explore new and somewhat unproven approaches."

ADDRESSING PATIENT ISSUES

Ms. Brescia says as patients continue to become more aggressive about researching their treatment options, including participation in clinical trials, there is tremendous opportunity to harness patient interest in new treatments and link this to clinical research.

"In certain therapeutic categories, such as oncology, nephrology, and rheumatology, we're already seeing the number of studies being conducted by a single site increasing significantly, often exceeding 10 or more simultaneous competing studies," Ms. Brescia says.

The foremost concern that patients have about participating in clinical trials is convenience, according to a recent Thomson CenterWatch research. Specifically, 54% of survey respondents cited flexible hours as their No. 1 concern upon entering a trial. The risk level with the procedures also ranked high, with 46% of respondents voicing concerns about the risk and invasiveness of the procedure.

PATIENT RECRUITMENT FACTS

THE RESULTS OF A RECENT THOMSON CENTERWATCH SURVEY SHOW THAT EFFORTS TO INCREASE PATIENT EDUCATION HAVE RESULTED IN POSITIVE OUTCOMES. INVESTIGATIVE SITES AND PHARMACEUTICAL SPONSORS ALSO CAN INCREASE THE COMFORT LEVELS OF THEIR VOLUNTEERS BY ADDRESSING THE LOGISTICAL, LIFESTYLE SIDE OF THE CLINICAL-TRIAL EXPERIENCE.

OTHER KEY FINDINGS:

- **92% of clinical-trials participants** rated their experiences as either good or very good; **91%** said they would participate in a trial again; and **87%** said they'd recommend that a family member or friend participate in a clinical study.
- **The top factors influencing** patient involvement with clinical trials were the goals to find a better treatment and to advance science.
- **60% of physicians surveyed** have referred patients to clinical trials. Those who have not referred patients into trials cite a lack of information about treatments as the No. 1 hindrance to participation. Just **7%** of physicians said they feared losing the patient.
- **The most common therapeutic areas** receiving doctor referrals were cardiology **(10%)**, oncology **(10%)**, and psychology **(7%)**.

Source: Thomson CenterWatch, Boston. For more information, visit centerwatch.com.

FACTORS IMPACTING STUDY PARTICIPATION

FACTOR	% RESPONDING
Because my family or friends recommended it	9%
Because my doctor advised me to participate	15%
To receive money for my participation	26%
To receive free medication and medical care	30%
To receive higher quality medical care	49%
To help myself and others to advance science	79%
To find a better treatment	79%

Source: Thomson CenterWatch, Boston. For more information, visit centerwatch.com.

information services company and a business of The Thomson Corp. For more information, visit centerwatch.com.

DARREN MCDANIEL, MS. CEO and Founder, Coast Independent Review Board LLC, Lake Forest, Calif.; Coast IRB is an independent review board that provides ethical and thorough review with an internal focus on quality and exceptional service. For more information, visit coastirb.com.

DENISE B. ROBINSON. Executive Director, Marketing, Inclinix Inc., Wilmington, N.C.; Inclinix provides pharmaceutical and biotechnology sponsors the tools necessary to complete enrollment of their trial on time and on budget. For more information, visit inclinix.com.

OUTLOOK:
IMPROVING PATIENT RECRUITMENT

PHARMAVOICE ASKED EXPERTS INVOLVED IN THE PATIENT-RECRUITMENT AND REVIEW BOARD SECTORS TO IDENTIFY THE BIGGEST OPPORTUNITIES FOR IMPROVING PATIENT RECRUITMENT AND CONVERSELY THE BIGGEST CHALLENGES.

Bonnie Brescia
BBK Worldwide

While randomization targets in the United States continue to decline, with more and more studies looking to Europe and South America for recruitment relief, study managers and investigators in these regions report increasing difficulty in reaching their targets without greater recruitment support.

On the flip side, patients continue to become more and more aggressive about researching their treatment options, including participation in clinical trials. There is tremendous opportunity to harness patient interest in new treatments and link this to clinical research.

David Fox
Praxis

The biggest opportunities for the patient recruitment sector will be for those companies to find new and creative ways to make patients aware of, and eager to, participate in clinical trials. Additionally, companies that can show metrics and a true return on investment for their clients will continue to do well.

The biggest challenge we will face in 2007 will be in overcoming the status quo. Somehow this industry has become acclimated to an 80% failure rate when it comes to patient recruitment. This is a failure rate that would not be tolerated in any other aspect of this or any other industry.

Darren McDaniel
Coast IRB

Unfortunately, the FDA recently removed the IRB 'shopping' guidance, which, in essence, is curtailing the ethical obligation and authority of IRBs to protect volunteer research patients. IRBs are overloaded with adverse events, and we are anxiously awaiting guidance from the FDA about this critical issue. These factors pose an ongoing challenge to an overburdened system that is much needed to protect research participants.

The greatest opportunity is in educating study sponsors that an excellent IRB oversight system will make their studies more profitable and not a cost center. In other words, by conducting ethical research with the patients' best interests in mind we all win.

The other opportunity is the use of data safety monitoring boards (DSMB). DSMBs are a must to help improve the safety of volunteer research participants in our studies and improve a system in dire need of reform.

Denise Robinson
Inclinix

Virtual medical records (VMR)-based technologies will begin to gain traction in outpatient medical-practice environments. VMR will be a breakthrough for patient recruiting as it will enable sponsors to objectively identify which investigators have patients in their practice who meet the inclusion/exclusion criteria for participation in a trial.

VMR will create an electronic gateway that will enable investigators to efficiently identify study candidates from within their medical practices while maintaining HIPAA compliance.

There is concern about the number of studies that have been postponed from 2006 into 2007 and about the impact this will likely have within the United States as there is even greater competition for the time and attention of qualified principal investigators and study staff.

Bonnie Brescia
BBK Worldwide

Another 46% showed concern about the risk of side effects.

Additionally, 31% were most concerned about the ability to reach the investigative site on public transportation, and 21% were concerned about keeping visits to a minimum.

"While the studies themselves are conducted according to the scientific method, the study subjects are often participating based on hope for a cure," says Mary Jo Lamberti, Ph.D., senior manager of market intelligence at Thomson CenterWatch. "Still, despite the strong emotional component, both trial volunteers and referring physicians seem to enter the clinical-trial decision with a logic-based mindset."

While there are a variety of reasons patients agree to participate in clinical trials, the single biggest priority for professionals who are involved in investigator trials is protecting those patients.

Institutional review boards are often the gatekeepers of patient safety, but recently these organizations, as well as other patient-related organizations, have become subject to a number of pending reforms before Congress.

"Reports come out daily from different groups about sweeping reforms needed within the medical research oversight system," says Darren McDaniel, MS, CEO and Founder of Coast Independent Review Board LLC. "The IOM has issued the most recent report with significant recommendations for overhauling the system. In summary, if we, as an industry, don't start governing ourselves, I foresee an 'Enron-type' catastrophe, which will cause serious damage to drug-development innovations." ✦

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