BY DENISE MYSHKO

PATIENT RECRUITMENT

The Continuing Saga of Patient-Recruitment BOTTLENECKS

If patient recruitment wasn't already hard enough, **LARGER, MORE COMPLEX TRIALS HAVE MADE THE ENROLLMENT OF PATIENTS EVEN MORE CHALLENGING**.

Dr. Julian Adams
Infinity Pharmaceuticals

Enrollment strategies that are mindful of a particular molecular genotype will better differentiate new patient therapies.

Clinical-trial patient recruitment and retention continue to be widely recognized as some of the leading challenges in drug development. Almost half of all trial delays are caused by patient-recruitment problems. These delays cost makers of specialty products more than $500,000 in lost sales and they result in losses of more than $8 million for blockbuster drugs, according to Global Business Insights.

Experts say the opportunities to improve recruitment success are ample. But the ability to be innovative in process improvements as well as technological enhancements will be critical.

It is becoming harder to recruit patients into clinical trials in North America and Western Europe because of increasing competition and the difficulty in finding patients who are not already on other therapies, says Missy Orr, executive director of patient recruitment at PPD Inc.

"As a result, pharmaceutical companies are expanding into emerging areas such as Latin America, Eastern Europe, and Asia," she says. "It is equally important to address and overcome protocol challenges and to adopt new technologies as a means of reaching the target population. Yet, no matter where a clinical trial takes place, it is critical to ensure that all patients are fully informed about their participation."

Given that there are many more drugs than ever before in clinical development in the United States and abroad, patient recruitment is far more demanding, says Julian Adams, Ph.D., president of research and development and chief scientific officer at Infinity Pharmaceuticals.

"Companies will need to create global capabilities for trial enrollment and ensure that patient enrichment strategies are associated with their trials," he says. "All-comer trials are cumbersome, and we often don't learn enough about safety nor about which patient population can benefit most from various treatments. Enrollment strategies that are mindful of a particular molecular genotype will better differentiate new patient therapies."

KK Rumrill, director of client operations, at BBK Worldwide, says something sponsors can and should be doing right now to improve patient recruitment timelines is to address country and site selection for trials using an enrollment perspective.

"With protocol analysis and country research, we can begin to build and rank a list of criteria that help to understand which countries have more or fewer enrollment barriers," she says. "Knowledge and measurement of

EXPERTS

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Denise Robinson *Inclinix*

Sponsors will need to carefully examine practices to ensure that the appropriate infrastructure is in place and adequate assistance is provided to sites to ensure their success.

KK Rumrill *BBK Worldwide*

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those enrollment barriers are absolutely critical to creating an overall recruitment strategy that will successfully enroll the study. Many sponsors rely on business objectives to drive country selection decisions. Although this is a fact of business that we may have to accept, it doesn't preclude good planning. By conducting country analyses, a sponsor will go in with a clear picture of the country's enrollment potential, or lack thereof, along with an informed plan to boost enrollment from the outset."

According to Steve Horstmann, president of ICD Global, the industry's move toward more global recruitment tactics is a proactive measure to address the challenge of patient recruitment, and one that will continue to evolve.

"Recruiting globally opens up the pool of participants for trials that just wouldn't meet recruitment numbers otherwise," he says. "Although multinational clinical trials can pose some new obstacles and logistical challenges for patient recruiters, it's the right direction to take. For example, if printed materials are the cornerstone of educating the public about a trial, special attention must be paid to cultural nuances and different languages. Having multiple versions of recruitment and marketing materials can greatly increase the amount of preparation needed to begin recruiting efforts, and then sites have to be armed with the appropriate materials to avoid timeline delays."

Sharen Godwin, VP of clinical patient messaging at Ateb, agrees that one of the biggest challenges in clinical research is providing education to the general population. She credits the Center for Information & Study on Clinical Research Participation (CISCRP) and several others for pioneering movements to address the educational gap.

"Opportunity persists," Ms. Godwin says. "We must counter the negative media attention with an educative response. The clinical-research education initiative should not be shouldered by the few industry giants working toward the higher goal. Rather, we should stand on their shoulders and help move their vision forward. The efforts of clinical-research study participants are significant. Through them our clinical-research trials take flight."

Because patient recruiting is so costly, retaining those patients proves just as critical to the success of a trial.

"Offering the right incentives and having study kits accessible to participants can help reduce dropout rates," Mr. Horstmann says. "Although the importance of these materials can be overlooked, it takes very little to deter a patient from continuing a study."

Ms. Orr agrees, saying patients have to be educated about their important role in advancing clinical research.

"Minorities, in particular, are underrepresented in clinical trials," she says. "In the United States, African-American, Latino, and Asian populations represent about one-third of all Americans, but these groups represent less

(CRO) providing discovery, development, and postapproval services as well as compound partnering programs. For more information, visit ppdi.com.

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Steve Horstmann *ICD Global*

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than one-tenth of U.S. clinical-trial participants. Study participants from all races and ethnicities are needed to evaluate the safety and efficacy of new drugs."

Denise Robinson, executive director of client services at Inclinix, says one of the most challenging areas of patient recruitment continues to be at the site level.

"Rising economic pressures affect staffing, facility resources, and ultimately time allocations to existing patients, as well as prospective clinical-trial participants," she says. "Sponsors will need to carefully examine practices to ensure that the appropriate infrastructure is in place and adequate assistance is provided to sites to ensure their success. The future of healthcare depends on these small businesses."

Julie Stein, Kforce Pfizer alliance operations director at Kforce Inc., says gone are the days of assessing a potential site based simply on investigator knowledge of good clinical practice (GCP), a competent study staff, and adequate monitoring space.

"Investigators must employ an all-of-the-above approach to identify and recruit subjects with the growing complexity of protocols and an often scarce supply of willing study participants," she says. "Often, study teams preselect sites based on trial knowledge or high recruitment in past studies, but it is the CRAs who are best suited to advise on which sites have the greatest propensity for patient recruitment and to assess if the site will truly perform. By empowering CRAs with some fundamental operations management skills they will be able to examine sites and provide evidence as to how to work with sites that aren't performing as well."

TECHNOLOGY STRATEGIES

Dr. Adams points out that data capturing and clinical-trial management will need to be centralized and sponsors will need to use cutting-edge technology to ensure efficiency and accuracy, which are particularly critical in a global research setting.

Mr. Horstmann agrees, predicting that with so many different sites around the world and stakeholders involved in the patient-recruitment process, Web-based software that allows individuals working on a trial to stay connected will be critical.

Ms. Godwin says technology immersion affects almost every aspect of clinical trials.

"Patient recruitment is inclusive in the movement to streamline processes facilitated by technology," she says. "There is now proven real-time direct-to-patient (DTP) or direct-to-consumer (DTC) messaging at the pharmacy point of care to those matching the study patient profiles. This is a recruitment game changer, where it is a 'best-fits' approach. Pharmacy outreach identifies the medication, dosing, and delivery mechanism and cross-references the age and location to present the study opportunity. Further prequalification is done via an interactive script with double HIPAA opt-ins and opt-outs."

Ms. Robinson agrees, saying powerful technology exists that will optimize each aspect of an individual protocol, from feasibility to compliance.

"These technologies provide a 100,000-foot view of a patient population, as well as a microscopic view into the available patients within site practices," she says. "The propagation of these technologies throughout sites and sponsors will result in data-driven decisions,

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PATIENT RECRUITMENT BY THE NUMBERS

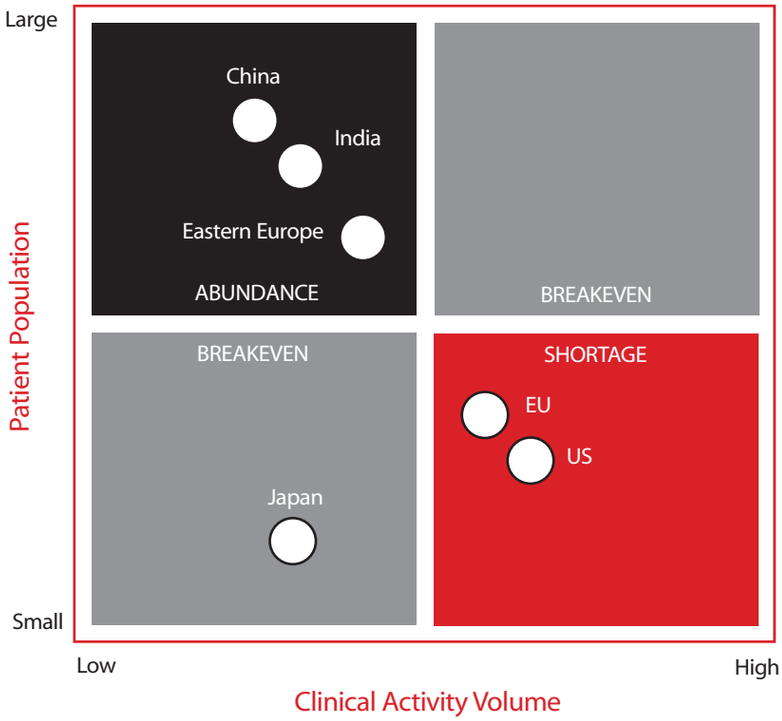
- **More than 2.3 million** people participate in about 80,000 total clinical trials every year throughout the United States.
- **50,000 to 60,000** of these trials are industry sponsored, while the remaining are government sponsored.
- **In the past 20 years**, the average number of patients per trial increased from 1,700 to more than 4,000.
- **The average number of participants** needed for a new drug trial jumped from 2,270 participants in the 1980s to 3,700 participants in the 1990s.
- **Studies have shown** that while 44% of people find out about studies through the media, only 14% gain the information from their physicians.
- **80% of total trials are delayed** at least one month because of unfulfilled enrollment.
- **In a recent poll, 94% of people** recognize the importance of participating in clinical research to assist in the advancement of medical science. Yet 75% of the general public state that they have little to no knowledge about the clinical-research enterprise and the participation process.
- **More than half of respondents** would have greater trust in clinical-research information if the results were made available on a public Website registry.
- **An overwhelming majority of people (77%)** say they would consider getting involved in an appropriate clinical research study if asked; but only 10% of those eligible to participate in clinical trials do so in the United States.

Source: CISCRP, Dedham, Mass. For more information, visit ciscrp.org.

PATIENT RECRUITMENT AND RETENTION IN CLINICAL TRIALS

EMERGING STRATEGIES IN EUROPE, THE UNITED STATES, AND ASIA

Supply of Clinical Study Patients by Region, 2007



Source: Busines Insights, London.For more information, visit globalbusinessinsights.com.

improved outcomes, and ultimately a purposeful change in the approach to clinical development."

Ms. Rumrill says sponsors want trackability and accountability.

"This extends to every area of the clinical-development process, including recruitment," she says. "Not only do sponsors want to track performance on a site-by-site and country-by-country basis, but they want to be able to use real-time recruitment data to make mid-course corrections and reallocate resources to improve recruitment outcomes. Patient recruitment companies are responding."

Ms. Godwin points out that there has been a surge in the use of Internet resources across the patient-recruitment continuum.

"For example, patient registries have become more sophisticated and yet easier to navigate for the patient," she says. "Study Websites are more accessible and provide better understanding about the trial. The innovative use of Web resources, such as online forums, have impressively broadened the landscape for patient recruitment."

A recent report from Datamonitor finds that optimizing the recruitment process through Web-based technologies can cut delays in clinical trials and can be used to maintain relationships with patients to improve the clinical-trial process. Because 90% of trials are delayed, and the majority of these delays are attributed to patient recruitment problems, Datamonitor analysts say a radical change is needed. One solution, they say, is a patient-centric approach through a Web-based platform. As it has minimal costs, the Internet can provide substantial cost savings and can reach populations all over the world at a remarkable rate.

The main barrier in using the Internet for recruitment is that often patients do not know where to look for information. To overcome this, Datamonitor analysts say, Websites must be user-friendly, with complete and up-to-date information that can be understood by the general public.

"While it is essential to develop custom-designed recruitment and retention programs for studies of all sizes and complexities, the Internet has become an important tool that provides information about clinical-research trials and potential investigators," Ms. Orr says. "The Internet also provides vital information for potential patients who are searching the Web to find relevant trials."

Ms. Stein says CRAs will begin using software programs that identify geographic clus-

ters of people who are suffering from the same disease.

"Thus they will be able to 'see' where the largest concentrations of potential patients exist," she says. "This will allow for more accurate identification of high-performing sites on a therapeutic basis."

OUTSOURCING FOR PATIENT RECRUITMENT

Ms. Rumrill says outsourcing partners will play a huge role in the future.

"Sponsors are outsourcing more and more to cut costs, calling for more strategic and collaborative partnerships between the different silos involved in patient recruitment — patient recruitment companies, clinical research organizations (CROs), advertising firms, and others," she says. "In the future, I believe sponsors will not only outsource more, but earlier in the planning process. I can foresee a time when they will, as a strategic and cost-cutting measure, begin to look at country feasibility and country planning earlier on. Additionally, sponsors will begin to employ more pay-for-performance measurements. For patient recruitment professionals, this means being able to track the value of outreach initiatives on a per-country, per-site basis. That level of accountability will be key to success. The good news is that, for the sponsor, having these data also helps ensure that the study is enrolled successfully."

Ms. Godwin says outsourcing key components that are not the study team's area of expertise or their best use of time to experienced experts is a smart and cost-effective strategy.

"Outsourcing can prevent unnecessary spending and tactical blundering and will continue to be a strategic trend," she says.

Ms. Robinson says outsourcing in the future should by synonymous with the term "value added."

"Sponsors will leverage each partner's expertise," she says. "In patient recruitment, identifying the partner that best suits the needs of the particular trial, or patient population, will be critical."

Ms. Orr says as pharmaceutical companies continue to expand their clinical-trial programs in emerging regions, they will rely on global contract research organizations that have experts on the ground in those regions.

"These experts have a strong understanding of patient recruitment and site selection strategies, as well as in-depth knowledge of local regulatory guidelines," she says. "CROs play an important role to ensure that clinical trials start on time and to control the costs of studies."

Ms. Stein says leading functional outsourcing providers will form fully dedicated study start-up teams that are therapeutically aligned to meet customer needs.

"These teams have first-hand knowledge and experience with sites that have the highest propensity for patient recruitment." ✦

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