Taren Grom

Unclogging the PATIENT RECRUITMENT BOTTLENECK

The increased complexity of clinical trial design and the trend toward more targeted patient populations necessitates rethinking the traditional methods of patient recruitment to overcome failure and timeline extensions.

Patient recruitment remains to be one of the biggest, and most costly, bottlenecks in clinical development. While the most commonly accepted recruitment mainstays are investigative site patient databases and advertising, industry averages reveal that more than 80% of clinical trials are delayed because of poor enrollment. So it stands to reason that the mainstay recruitment practices may require retooling or additional tactics to meet the demand for qualified participants.

Industry insiders admit there is no one answer to solve this ongoing challenge, and with the increased complexity of clinical trial design, the trend toward more targeted patient populations and the growing movement toward emerging markets for clinical trials, the traditional methods of determining feasibility and developing patient recruitment plans will only lead to failure and timeline extensions.

Patient recruitment is not the first step in a clinical trial, but well-designed recruiting could be the most important piece, say analysts at Cutting Edge Information.

"Companies have only scratched the surface of the potential benefits of deep patient understanding to more accurately develop protocols that will meet enrollment targets," says Jason Richardson, president of Cutting Edge Information.

According to a recent Cutting Edge Information study, Clinical Trial Patient Recruitment: Accelerate Enrollment, Increase Retention and Reduce Costs, 72% of respondents perform preproject research into patient emotion and motivation, but much of that research is only surface deep.

"The more information trial designers have about the patient population, the more likely they can design a study that meets all enrollment goals," Mr. Richardson says. "More nuanced demographic research saves dollars as coordinators can put limited funds into the right recruiting channels."

Thinking like a patient, he says, means heavily weighing emotional motivators. Sponsors and CROs should consider the following: are patients embarrassed by their condition, will daily office visits be too painful a reminder that they are living with the disease, will they feel altruistic in joining a study, and will the opportunity to increase the scientific understanding of a disease resonate with them?

Cutting Edge analysts say experienced patient recruitment specialists are better prepared to address such issues, and may push for additional office visits, for example. Recruitment specialists can identify the point at which site visit frequency will increase drop-out rates. In such situations, the team can identify the best trial protocols to meet the needs of all stakeholders.

In its recent report, Cutting Edge identified five key findings and recommendations to improve how patient recuitment is approached:

- Patient retention strategies are undersused by the healthcare industry
- Evaluate potential sites and investigators to improve patient recruitment
- Tap into patient motivators, such as altruism, improved/free treatment, and convenient protocols to speed up the patient recruitment process
- Set a patient recruitment budget
- Enter a strategic partnership with a CRO with patient recruitment experience

Keep Site Requirements in Sight

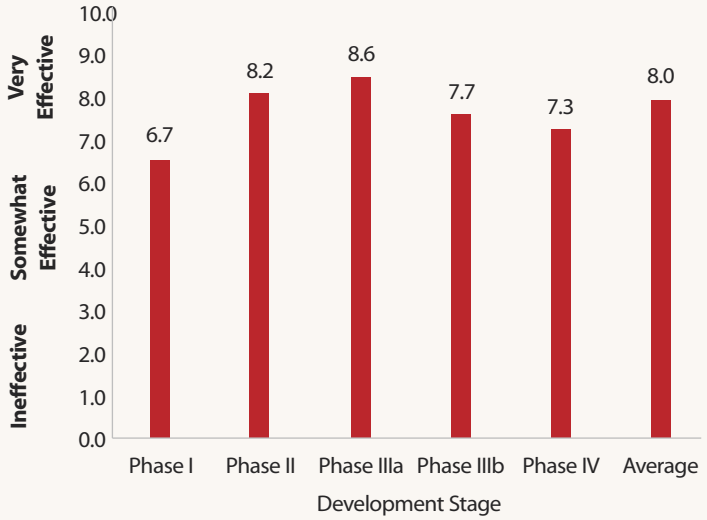
Experts say site evaluation is one of the most important activities related to patient recruitment. One of the biggest challenges is making sure sites are equipped to manage the trials. Sites must provide an accurate picture of the types of patients that they treat, their ability to manage a clinical trial, and the expertise of their staff.

While sponsors recognize the importance of evaluating physicians and sites for patient recruitment, analysts say rarely is the trial protocol detailed enough for sites to respond accurately to an RFP. As a result, most sites will overstate their ability to recruit patients.

According to research by Citeline, poor selection of trial sites, largely because of a lack of knowledge of active and relevant clinical investigators, is increasing the cost of clinical trials by 20% or more.

In a blind test, Citeline compared the experience and track record of selected investigators for four clinical trials and found that on average the trials used 20% more investiga-

EVALUATING SITES AND INVESTIGATORS BY PHASE



Source: Cutting Edge Information. For more information, visit cuttingedgeinfo.com.

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VIEWPOINTS

A risk mitigation strategy

The greatest recruitment risk mitigation strategy utilizes a CRO partner that thinks like a recruitment firm, a site, and a patient but operates like a CRO. Budgets, resources, staff equally supporting one another and sharing a patient-centric focus enhance control over the ability to deliver quality and exceed timeline expectations.

LEE BARSKY, VP, CRO Services
Accelovance

Global feasibility

Without a comprehensive understanding of country-specific limitations and advantages, clinical teams will handicap their ability to effectively recruit subjects. Country and site feasibility provide empirically grounded direction on recruitment and retention strategies, which is best performed by recruitment experts with the know-how to validate all findings.

SANDRA CHASE, VP, Operations
Healthcare Communications Group (HCG)

Achieving operational efficiency

Pharma R&D units have been facing ever rising clinical trial study costs and mounting time pressures. By utilizing comprehensive secondary data sources and analytics, R&D organizations can improve their patient recruiting productivity by identifying the most relevant patient populations around the globe.

MICHEL DENARIÉ, Leader, Center of Excellence, Customer Insights
IMS Health

Putting e-marketing into practice

The most important best practice of the moment for achieving operational efficiency is undoubtedly the integration of e-marketing/Internet advertising/social media into patient recruitment programs. Not only can it deliver significant savings in terms of cost and time, but it also makes it far easier to track success in real time.

LIZ MOENCH, President & CEO
MediciGlobal

Sites are pivotal

Sites often aren't engaged or given the resources to successfully enroll. They may not be focused on your trial, and therefore potential patients are overlooked. Site-based strategies and in-field enrollment resources support the sites and ensure that outreach tactics — online, traditional, or community-focused — are effective and ultimately enroll patients.

CHRISTOPHER W. SLEAT, Chief Marketing Officer, *Inclinix Inc.*

Enhancing patient productivity

Pharma companies and CROs are entirely reliant upon sites, but do not possess the expertise to help them reach their enrollment goals. Sites and their sponsors need and want help through a set of services focused on enhancing their patient productivity.

ROGER D. SMITH, Senior VP, Operations
Acurian Inc.

tors than were actually needed to achieve the required patient targets.

In one example, for a Phase III oncology trial requiring 930 patients, the sponsor used 137 trial sites, of which more than half failed to recruit more than five patients per site.

Database-driven site selection is still a relatively new but powerful option for the pharmaceutical industry, as most trial sponsors rely heavily on their relationships with previously used sites to find suitable investigators.

According to Dr. Jamil Hussain, senior VP, clinical development, at Citeline, relying solely on a company's own database of successful past experience is far from the most efficient approach.

"In these challenging financial times where drug companies need to contain every cost and delay to maximize profit, improving site selection presents a very big opportunity to make an instant and substantial saving," he says.

According to Gretchen Goller, patient recruitment and compliance strategist, operations, at Sanofi-Aventis, with today's ongoing enrollment challenges, it is imperative that sponsors and CROs be open-minded with regard to planning their enrollment.

Ms. Goller adds this is specifically important when determining what research sites are the best fit for any given protocol; academic medical centers, SMOs, and other nontraditional research sites should be considered as viable options as well.

A key to site evaluation is learning about the patient population that the site has access to. One method for accurately assessing the patient population leverages electronic medical records (EMRs).

Understanding the true recruitment capabilities of a potential site is the most important activity a sponsor can do. PV

EXPERTS

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JASON RICHARDSON. President, Cutting Edge Information, a provider of innovative, implementable research and consulting to the pharmaceutical, biotechnology, and medical-devices industries. For more information, visit cuttingedgeinfo.com.

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