

# Patient Recruitment: The Most Recognized Silent Driver of Clinical Development Costs



**In today's competitive pharmaceutical industry, the contest to recruit patients into clinical trials may be fiercer than the race to discover the next blockbuster.**

Patient recruitment challenges the drug development process for a number of reasons. First, the fallout from Vioxx and Bextra's recalls in 2005 caused regulatory agencies worldwide to increase requests for additional safety data prior to drug approval. These additional safety requests have exacerbated an existing patient recruitment problem among drug manufacturers. And in some cases, regulatory agencies request that companies initiate new clinical trials. A significantly increased demand for clinical trial patients, combined with the relatively flat growth in clinical investigators and study sites, places the pharmaceutical industry in a predicament: The demand for clinical trial patients has begun to outpace the supply.

This increased need for clinical trial volunteers has led to the expected economic effects when demand outpaces supply — trial costs have risen. Among Cutting Edge Information's surveyed drug manufacturers, 32% cite patient recruitment as the largest driver of increased clinical trial costs. Increased vendor fees — largely a result of the growing competition for clinical study sites — also trigger higher clinical costs.

An increasing number of trials across the board means that more and more companies want to attract the best-performing contract research organisations (CROs) and sites — spiking clinical development costs. Likewise, finding CROs and sites that are not recruiting against themselves by hosting several similar studies is proving challenging, and thereby expensive.

## Dedicated Resources: The Keys to the Patient Recruitment Kingdom

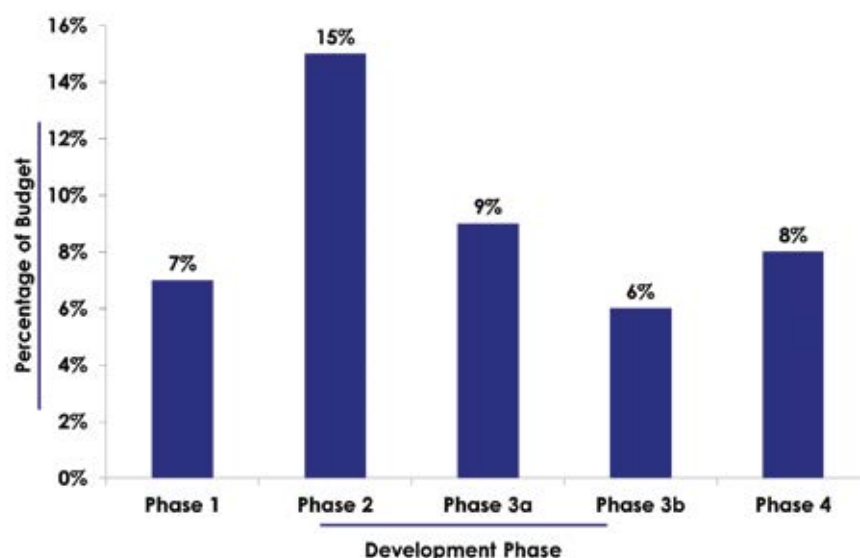
Drug companies readily recognise

that patient recruitment is a top challenge for clinical development. However, few companies focus time or resources toward overcoming even the most common patient recruitment roadblocks.

“Clinical operations staff are well intentioned, but they are not always familiar with the latest or even standard practice patient recruitment

those budget allocations range from 6% to 15% of the total trial budget, depending on the development phase. With life science companies facing the increased demand for patients, even these percentage allocations lead to shortfalls. Further, many companies do not even allocate patient recruitment funds to circumvent the increasing demand.

**Average Patient Recruitment Budget Allocation by Phase (Sponsors/CROs)**



activities,” said one former senior director of recruitment strategy at a top 10 pharmaceutical company. What these employees have in clinical perspective, they often lack in the marketing skills necessary for a strong recruitment drive. In addition, many clinical staff work on a trial every two or three years. These staff experience longer ramp-up timelines compared to dedicated patient recruitment staff that can enlist patients for many studies at once.

Despite the significant costs associated with patient recruitment — and even though clinical trial managers often cite it as the top challenge — few drug companies dedicate enough resources to solve the problem. According to Cutting Edge Information's survey data, among drug companies that do dedicate funds for patient recruitment,

One reason that clinical trial sponsors consistently face recruitment challenges is that they often do not set recruitment budgets for their studies. These sponsors also neglect to hire anyone to manage the patient recruitment part of the clinical process. Only 15% of the drug manufacturers surveyed have dedicated patient recruitment groups in place.

The first best step to equip a clinical development team with tools to overcome recruitment obstacles is to dedicate resources. At companies that do not have a patient recruitment group but hold a specific person or group responsible, the task typically falls to the study manager. At one organisation profiled by Cutting Edge Information, the study coordinators are responsible for recruitment, but they also receive assistance

from other internal groups. Each month a committee meets with site physicians who are not involved in the study. These meetings make the physicians aware of the various research opportunities available to their patients and encourage them to refer patients to different trials.

**Site Management:  
Asking the Right Questions**

The fact is, however, many drug companies' clinical development strategies do not plan for patient recruitment. Some companies rest on

sites to overstate their ability to recruit patients to win the business.

This scenario may lead to success in the short term. But further problems may arise if, months later, the completed trial protocol reveals that patients must comply with four or five additional criteria unknown to the sites during the RFP process. Drug manufacturers and their CROs should aim to provide sites as many details as possible so that sites can better evaluate their recruitment potential.

As part of the site evaluation process, learning about the patient

small practice that sees 35 patients a day could be at maximum capacity and would need to hire additional employees to be a successful trial site.

**Patient Retention:  
The Silent Challenge**

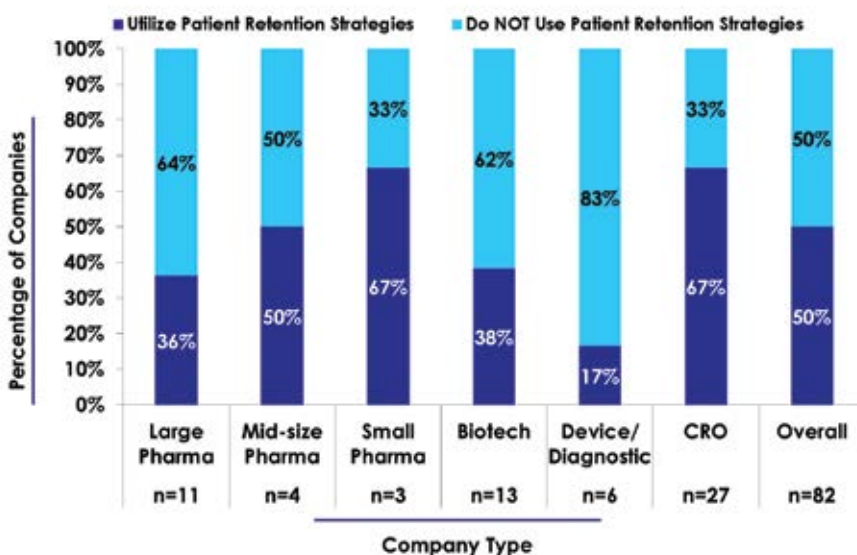
None of the aforementioned issues address the secondary challenge facing clinical trial teams: patient retention. Even though they face problematic patient recruitment numbers, drug companies underuse patient retention strategies. Cutting Edge Information's patient recruitment study found that a staggering 64% of large pharmaceutical companies surveyed do not implement any patient retention strategies, despite having more resources to do so. Furthermore, patient dropout rates can be unpredictable. With that in mind, more conservative trial designers will factor in a 30% dropout rate into their enrolment goals.

Patient retention relies greatly on trial duration and protocol, however. Shorter trials do not have the same patient retention issues as do longer trials. For longer trials, protocol should deliberately include patient retention strategies. Many clinical development executives interviewed for Cutting Edge Information's study believe that the most effective strategy to enhance patient retention is to make clinical trial participants feel engaged with the site staff. Sometimes the best patient retention programme is an adept study coordinator who can give patients personal attention and make them feel like a part of something larger.

Making patients feel special is not difficult, but it does require thought and effort. Study coordinators must consider both the physical and emotional aspects of participating in a clinical trial: How are the patients responding physically to the treatments? Is there any way to make them feel more comfortable? Do follow-up visits trigger an emotional reminder to patients that they have the disease? Trial coordinators with a strong grasp on how to handle those questions will be the best defence against patient dropout.

Cutting Edge Information's

**Percentage of Companies that Use Patient Retention Strategies by Company Type**



the hopes that their trials are enticing enough that patients will find them on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) or similar clinical trial directories, and enroll in a study. Others simply outlay a lump sum to their CROs and site management organisations (SMOs) and rely on these vendors to recruit patients.

Often, it is the sites that point out deficiencies in the sponsor companies' plans (or lack thereof) for patient recruitment. Clinical trial sites point to the request for proposal (RFP) process by which they land trial contracts as one source for poor recruitment strategies. Often during the RFP process, the details that trial sponsors provide sites about the trial protocols are vague. Sites must then use these imprecise details to make the best estimate for their costs. In these cases, the process encourages

population to which the site has access is key. Electronic medical records may help in this process as they become more prevalent. By scanning their electronic patient databases, sites can more accurately determine whether they believe they will recruit enough patients into clinical studies.

But patient recruitment involves much more than identifying sites with the correct population. Sponsors and CROs also need to evaluate the site's capacity to conduct the trial in the first place. To assess a site's capabilities, sponsors or CROs must look at the site's research history and performance and ask critical questions. If the site wants to perform its very first clinical trial, will it hire an experienced site coordinator? Will the site have time to assist in patient recruitment? For example, a

## CLINICAL/ MEDICAL RESEARCH

research uncovered examples of trial coordinators engaging patients and addressing their needs. In one diabetes trial, a study coordinator gave patients a special cookbook to help them handle their new dietary restrictions. Another trial manager made sure to send birthday cards to all study participants. Small, inexpensive gestures like these remind trial participants that the staff cares for patients' health first and foremost.

Several interviewed clinical trial executives discussed another retention technique: reminding trial participants that they are not alone. For example, newsletters that update the trial's progress around the world help to create a sense of connection among patients. Similarly, a web portal that allows patients to share their experiences with other study participants can keep them engaged in the trial process.

Ensuring that each and every patient completes the trial is a key to reducing total costs. Opening recruitment again after enlisting the last patient can crush a trial budget. With that in mind, it is surprising that 50% of all Cutting Edge Information survey respondents chose not to practice patient retention strategies.

brought in to close the gap. The second most popular reason for outsourcing to CROs is a trial that is too large or geographically broad to be managed by internal staff.

Large pharmaceutical companies have experience in running many trials concurrently.

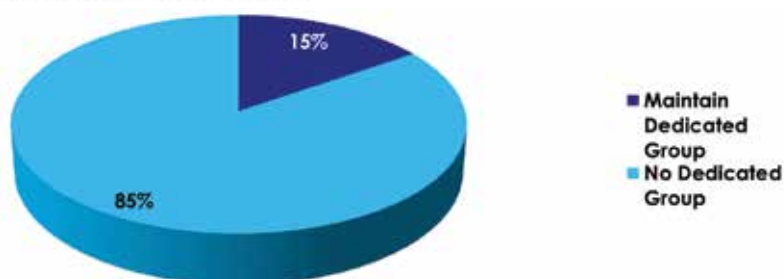
Few large drug companies, if any, outsource patient recruitment to CROs. All recruitment is managed internally at 89% of the surveyed companies in Cutting Edge Information's study. On the other end of the spectrum, 67% of small companies and 50% of biotech firms surveyed outsource patient recruitment to CROs. The vast majority of mid-sized and small drug manufacturers, however, do not have dedicated patient recruitment teams. The most sensible option to expedite trial enrolment for these companies is to hire a CRO to complete the task.

Compared to small drug companies, CROs are far more likely to have a group dedicated to patient recruitment. CROs also rely on their marketing teams to develop promotional strategies to boost patient enrolment. Many drug companies' marketing teams are often too busy promoting branded products to allocate resources to a developing compound. Furthermore, the possibility of mistakes

of millions to billions of dollars in lost sales. The approach of "if we conduct it, the patients will come" is inconsistent with clinical research goals. Clinical research goals should incorporate rigorous processes to identify and target patient populations.

And considering the potential costs of trial delays or even failures, study sponsors should increase their focus on implementing best practices to overcome patient recruitment challenges — and setting an adequate patient recruitment budget is an important best practice. Successful patient recruitment requires an investment of time and money that many drug companies rarely consider when setting a clinical trial budget. Cost-conscious sponsors may skip important aspects of the recruitment process, including patient demographic research. The same occurs with patient retention strategies; once patients are recruited, study sponsors may think the job is complete. But extra investment during the patient retention phases rewards forward-thinking trial managers. Taking adequate time to evaluate sites and spending money on additional tools — or even CROs — will accelerate patient recruitment, eliminate delays, help to meet target enrolment and, in many cases, ultimately save money.

### Percentage of Companies that Maintain a Dedicated Patient Recruitment Group



#### Outsourcing Patient Recruitment: The CRO Solution

Time is money in the clinical arena, as trial delays mean a later-than-expected product launch. Using CROs shortens the time required to complete enrolment. According to Cutting Edge Information research, the most commonly cited reason for a drug manufacturer to outsource patient recruitment to a CRO is that the company had previously encountered difficulties in achieving the enrolment targets set for a trial. A CRO is then

is especially strong for clinical teams lacking patient recruitment experience; this scenario is more likely in smaller companies with few or no marketed products. Therefore, although CROs offer patient recruitment advantages to companies of any size, they stand to benefit smaller companies the most.

#### Conclusion

For blockbuster drugs that generate billions of dollars in annual revenue, a six-month delay due to poor patient recruitment could cost hundreds

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