

Developing Effective Patient Communication Campaigns

Communicating to Maximise Patient Recruitment

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Your time to market is ticking away, your clinical trial has stalled as patient enrolment is slowing, everything is in place but you can't get the patients, what do you do?

It's a question asked by companies time and again when they realise that slow patient recruitment means their study is 'in rescue'. Data from a CenterWatch survey¹ revealed that in 40% of clinical studies, failure to achieve patient recruitment and retention targets was the biggest cause of delays. Problems such as this have been estimated to cost drug companies up to US\$1 million a day in missed sales revenues.² As shown in Figure 1, delays in clinical development reduce the time during which a company has the greatest market share before the patent expires and results in reduced revenue. Increasing the speed of patient recruitment and retaining those patients in clinical studies is of paramount concern to companies aiming to bring products to market with maximum efficiency.






Checklist	Points to consider
 Service provider's track record	Ensure the agency you consider has enough experience to understand and prepare for all of the issues that may arise during a trial. Such issues may relate to protocol detail, sites or patient challenges.
 Capacity to meet tight deadlines	Flexibility and quick responses are necessities for successful recruitment efforts. The speed at which an agency responds to your initial enquiry will indicate whether they understand the demands that you face.
 Consensus on forecasting model and cost assessment	The agency should proactively prepare recruitment forecasts. These forecast numbers form the backbone of the strategy and budget. Recruitment budgets should be based on critical data and information that you provide to the agency.
 Provision of metrics	Agencies need to be able to provide regular status updates and metrics in order to ensure maximum return on investment.
 Media buying approach	Media should be purchased at frequent intervals, every two to three weeks, based on metrics that continuously track site performance and not bought in advance in bulk to save money. Is your agency listening to your needs?

Figure 1. Delays in clinical development result in reduced revenue for sponsor companies.

There are many reasons for delays, including issues relating to the protocol, understanding the idiosyncrasies linked to differing

therapeutic areas and the cultural differences between countries in multi-centred trials; these are just some of the factors that can affect patient recruitment.

Thinking through the protocol from the patient's perspective is the first step. For example, if patients need to undergo specific procedures where ordinarily they wouldn't have to, this is likely to make it difficult to recruit. Whether patients exist in the areas that you are targeting is another obvious question. Feasibility on-site is critical: do your investigators have access to patients and are patients local to them? Is the site a hub centre? Bigger hospitals can, where appropriate, be selected in preference to smaller sites as they have access to larger pools of patients. Seasonal impacts also need consideration, where conditions such as hay fever or depression are relevant.

Clinical patient experiences can also vary between countries. The motivating factors behind a patient taking part can be directly related to the health services to which they have access. Those who do not have access to the latest medication or low-cost treatment will be more likely to take part in a study compared to those who do have easy access to high quality services. Patients may take part simply because they will gain access to a professional consultation, even if they may only be enrolled onto the placebo arm of a study. This consultation period can offer a level of assessment patients may not normally have access to.

The nature of individual therapeutic areas also affects recruitment. For example, in cases where patients have a chronic condition, they will already be in contact with the investigator sites themselves. In these cases it is essential to maximise recruitment through the sites and put an emphasis on communications materials to support investigators. In other examples where patients are found within the

community, such as with asthma or depression, techniques involving active outreach through the media may need to be employed. Within areas such as paediatrics or geriatrics, where carers and family members play a huge part in the decision-making process, correctly targeted educational materials are paramount.

Planning early on in a recruitment campaign gives companies the opportunity to approach patients using informative and measured communications techniques, which then enable them to take part in clinical trials. Patients share experiences within their family and other social support groups so it is important to do a good job from the start.

Competition for patients

The environment for recruitment of patients is changing and evolving all the time and competition for patients, especially for those with highly specific conditions, is intense. Patients are also becoming increasingly savvy with access to healthcare information via the internet and it is essential to provide them with enough detail to answer the majority of their questions through well-designed and sympathetically-written patient materials.

Development and understanding of clinical research has extended across the globe. A few years ago Eastern Europe was touted as the answer to recruitment woes, with many patients available through sites that had not been previously targeted for studies. With great access to patients, lack of competition, lower quality healthcare systems and the need to pay for medication, Eastern Europe provided a new pool of patients that are potentially more willing to participate in clinical studies. However, new markets can also bring their own challenges, such as whether sites own the right equipment to carry out protocols, as well as logistical hold-ups with importing drugs into these countries; but these can be tackled head on and problems soon ironed out. As a result of Eastern Europe's popularity as a recruitment resource, sites have become more sophisticated and patients have become more savvy, again creating a more competitive environment for investigator and patient recruitment.



Wherever a study is conducted, a key factor in the decision-making process of a patient is the educational material that they receive and how well informed they are about a clinical trial. As an example of why comprehensive educational materials are a necessity, Nelson et al³ find that parents approached for permission to allow their child to participate in a research study had less than optimal understanding of the elements of consent. Therefore, investigators must make every effort to enhance understanding and ensure that parents/patients have sufficient information to make informed decisions. With an increasingly competitive patient recruitment environment, this illustrates the need to build in effective programmes, both for direct-to-patient communications and for communication to site personnel. Patient

advertising and education programmes can be developed for all studies and indications in order to successfully recruit patients into studies across the globe.

Recruitment tactics

As discussed above, planning is key when it comes to recruiting and retaining patients in a clinical trial. It is essential to understand all the issues involved in recruiting for your study. It is relatively common for investigators to over-promise the number of patients that can be recruited. A detailed feasibility assessment of a site is essential prior to commencing a recruitment campaign, including a calculation of the number of patients that investigators can genuinely access. There are many reasons for over-promising delivery of patients, which may include financial incentives, or a 'disconnect' with those doing the job on the ground; for this reason, the data provided by a site should be fully interrogated in order to ensure that expectations are realistic.

Recruitment tactics divide into two broad aspects: maximising the recruitment of existing patients and outreach to new potential patients

Maximising recruitment of existing patients

It is most cost effective to target patients that sites already have access to. For example, in oncology, patients are already on site databases and these are usually sufficient for a study. There are also ethical issues

that affect the use of advertising where the subject material is very sensitive. In these cases, it is essential to use tools and aids to motivate investigators to recruit for you and keep your study 'top of mind'.

Site databases provide investigators with the ability to review every patient on their list to identify suitable candidates. To ensure that investigators make your study a priority over your competitors', site support packs can be created including information-based materials designed to make recruitment easier and more efficient. Simply providing materials with details about your study in an easy to access format ensures that investigators have information about your study to hand when it is needed. This can make a huge difference at a key moment when meeting and informing patients about the options available to them.

Outreach to new potential patients

When using outreach advertising as part of a recruitment campaign, it is essential to be sensitive to cultural differences. Keeping patients in mind, wording in print or via other media needs to be information-based and subtle in order to appeal to patients. Cultural differences may result in use of artwork which seems innocent in one country but which may be deemed too risqué in other countries, such as the use of an outline of a body. An ethics committee comprised of a selection of representatives including laymen must review materials to ensure they are not considered coercive and that they are honest and factual, before they are distributed to patients.

Support materials developed purely for use by investigators and study nurses do not require review by an ethics committee, which allows site support to be initiated as soon as a recruitment campaign has begun. Therefore recruitment support can still be provided soon after site initiation, even for sites that are subject to lengthy ethics review periods.

Recruitment communications campaigns

In the USA, use of sophisticated clinical trial recruitment communications campaigns have been in place for many years. This practice has been evolving over time in countries outside the USA, as different techniques and tactics become accepted. Europe followed suit and sponsors regularly take on new approaches and techniques initially adopted in the USA. Increasingly, such recruitment strategies are

also being employed further afield, as the recruitment challenge and resulting need for recruitment support spreads.

More and more companies are opting to use global communications programmes that are planned centrally and then implemented locally. As long as local cultural issues are taken into account, the same communications techniques and materials can be translated and used on a country-by-country basis.

However, what if a sponsor company is overstretched and does not have enough people to roll out a communications campaign to ensure adequate patient participation? The answer can be to outsource to a recruitment communications service provider. In order to outsource a recruitment campaign a pharmaceutical company needs to consider a number of issues including; the service provider's track record and experience, their geographical reach, their capacity to meet the company's tight deadlines and most significantly their ability to listen and understand the sponsor's requirements. See figure 2 for more details about consideration relating to outsourcing a clinical trial recruitment project.

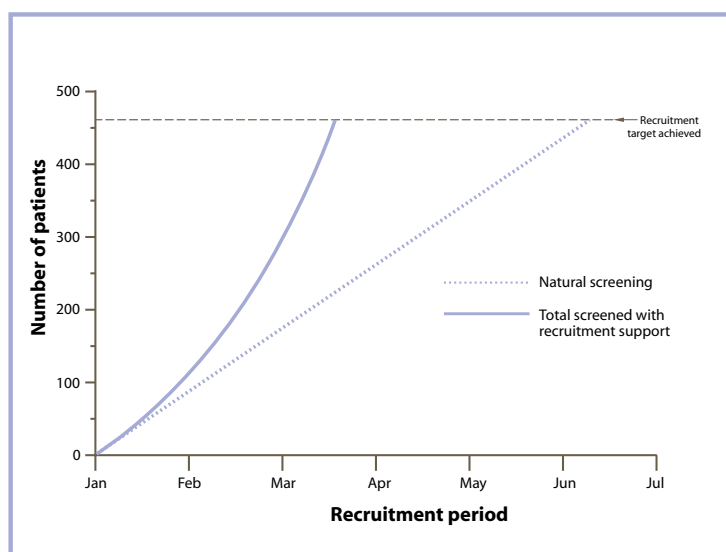


Figure 2. A pharmaceutical company needs to consider the following areas when planning to outsource a recruitment campaign to a specialist agency.

It is becoming increasingly common for sponsor companies to use specialist consultants who can implement communications campaigns as a cost-effective recruitment solution. Where sponsors were previously seeking help once a study was 'in rescue', companies are now planning ahead

in order to prevent this from happening and to maximise their return on investment. Many now have experience of the success of using communications campaigns. Figure 3 illustrates the difference an effective communications campaign can make to a study showing the impact they can have on predicted vs. actual recruitment rates.

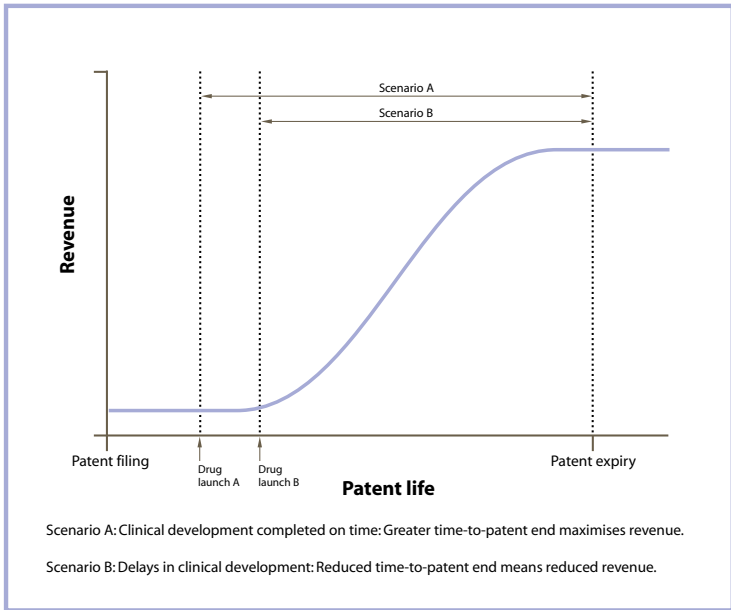


Figure 3. The impact of a communications campaign on the ability to reach recruitment targets for a Phase 2 virology study.

Keeping your study ‘top of mind’

As the clinical trial patient recruitment landscape enters an ever more competitive environment, communications campaigns will need to become increasingly sophisticated to guarantee their effectiveness. The tactics necessary to stay ahead of the competition and the need to provide a good service for patients within clinical studies has created a trend towards using specialist agencies to carry out complex and strategic communications campaigns. In the race to recruit and retain patients the core question remains, how can you stay ahead of your competitors in your clinical study? The answer can only be to ensure that you are planning and implementing your strategy ahead of time; only then will you ensure that your timelines are met and your study is kept on track. In your planning stages, you can then assess whether you have the necessary resources to implement a world-leading recruitment drive to ensure that your study is ‘top of mind’ with investigators and ‘first on the list’ for the patients you need to bring onboard.

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