MakroCare
New Possibilities, Everyday
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Patient Recruitment and Retention Planning Tool

Dr. Sreedhar

Points to Consider about Recruitment and Retention While Preparing a Clinical Research Study
(Questionnaire for planning Recruitment and retention).

1. Community Engagement

- Have you identified the communities that you would like to engage?
- What relationships have you established with communities in order to facilitate your study? What relationships will you need to establish?
- How will you maintain these relationships?
- What strategies will you use to engage different communities before and during your study?
- What efforts has your University/Research Institution made in the past to engage these communities? Are there any ongoing collaborations/partnerships at your institution?
- What will the participating communities receive in return for their involvement in the study?

2. Benefits to participation

- What are the benefits to enrolling in this clinical research study, from the perspective of potential participants? How will you determine these benefits?
- Does the study design include assessment/treatment strategies that are likely to foster enrollment and retention?

3. Barriers to participation

- What are the barriers to participation?
- How will you prepare to address each of these barriers?
- Will all study costs be covered for the participant? Is there a way to reduce any costs?
- Have you considered the language requirements and literacy of proposed participants?
- Are you familiar with how English is used by different racial and ethnic groups?

4. Informational materials

- Have you designed your informational/study materials for your intended audience?
- Have you considered working with community organizations that could help prepare, design, or distribute informational/study materials?
- Will study materials (consent forms, study instruments) account for different levels literacy and cognitive abilities?

5. Planning and Timeline

- What is a realistic recruitment timeline?
- What is your timeline for protocol finalization, IRB approvals, development of treatment materials or experimental methods, piloting, staff training and certification, development of data collection instruments and systems, tools for quality control, acquisition of treatment products and matching placebo, etc.?
- Do you plan to match resources to recruitment over the lifespan of the grant (i.e. funds, personnel)?
- What resources will be required to retain participants after the recruitment phase is completed?
- Have you considered using available local data to generate enrollment/retention estimates that are as accurate as possible?

6. Recruitment Strategies

- What mechanisms will you use to encourage recruitment?
- Will you need different recruitment strategies tailored to different racial/ethnic populations?
- Do you have a Public Affairs or Media Relations Department at your university that can help you to promote the study to your local media and community?
- Does your Public Affairs or Media Relations Department have connections to all of the communities chosen for the study?
- Do you have a detailed and piloted plan for community outreach for each group chosen?
- How long does it take your IRB to review and approve advertising?
- Will you have a dedicated telephone number and/or email address for potential participants to learn more about the study and a response system in place?
- Have you determined if there are conditions in the local community that might affect participant support of your project (e.g. the effects of numerous studies and over-sampling, or community activists seeking to influence research projects)?

7. Retention Strategies

- How will you retain participants?
- How will you monitor retention?

8. Diversity

- Do you have realistic recruitment and retention strategies for all populations, especially participants with diverse ethnic, racial, and socioeconomic backgrounds?
- Do you have an adequate mix of ethnic, racial, and economic diversity in your community from which to recruit participants?
- How do you plan to recruit different racial/ethnic populations?
- Do the backgrounds of senior study staff reflect the diversity of the communities that you wish to engage for participation in the study?
- Are you training your staff to be sensitive to cultural, racial, and ethnic differences?
- Are you aware that some communities are mistrustful of medical research? How do you plan to address these concerns? Will your research team work with peers who are knowledgeable about the community?
- Are you planning to work with organizations that interact or advocate for diverse populations?

9. Staff

- How do you plan to train your staff to perform the study protocol?
- How will you train staff to assume greater responsibility/independence?
- How will you replace key staff, if other staff members are not sufficiently experienced and/or trained to assume those responsibilities?
- How will you maintain "staff balance" for this study/trial (i.e. assigning staff among various trials)?

10. Multi-site considerations

- What is the maximum number of participants that your site has the capacity to screen, enroll, and follow up with at the same time?
- Have you chosen sites that can access the target populations and have a realistic likelihood of recruitment success?
- How will you train and certify staff at all clinical sites?
- How will you ensure that your sites will adhere to a common protocol?
- Are there plans for ensuring and monitoring fidelity to the protocol?
- Do you have plans for “backup” sites, should they become necessary?
- Have you considered the impact of potential unbalanced enrollment across sites?
- Have you specified conditions under which a site may be terminated?

11. Coordinating center for multi-site studies

- Does the coordinating center(s) have expertise in multi-site leadership?
- Do the coordinating center leaders have a clear mandate from site investigators?
- Have the leaders demonstrated a capacity to make decisions and keep the project moving forward?

- Does the coordinating center senior research team have the ability to assess and advise in matters concerning racial and ethnic diversity?
- Have you outlined the organizational structure (e.g. committees) of the coordinating center?
- Has the administrative structure and function been clearly defined?
- Do you have processes for resolving disputes and disagreements?

12. Sample Size

- Is the design flexible enough to permit enrollment of a diverse sample?
- Are the inclusion criteria too narrow, such that you will have unusual difficulty finding people who qualify for the study?

13. Institutional Review Board (IRB) and Data & Safety Monitoring

- Are the risks to participants minimized as much as possible through sound research design and the use of safety-focused procedures?
- Are participants selected fairly?
- Is a plan in place for seeking and documenting participants' informed consent? Are consent documents culturally and developmentally appropriate for all study populations?
- Is the informed consent document both legally and ethically sound?
- Have provisions been made for monitoring the data collected to ensure the safety of participants as the trial progresses?
- Have provisions been made to protect the privacy of participants and the confidentiality of data collected during the study?

14. Pilot Studies

- Have you piloted all relevant aspects of the methodology including recruitment, screening, assessment, randomization procedures (if required), treatment and experimental methods, data entry, etc.?
- Has retention of participants been achieved for pilot studies? For how long?

15. When the study has been completed

- How will you thank participants?
- How will you disseminate the research results to all communities involved?
- How will you maintain the relationships that you have forged with the communities?

Patient recruitment solutions an internet based community approach

Dr. Sreedhar

"Targeting the right people in the right way will keep trial numbers high"

Researches managing clinical trials will sight patient recruitment as their single most difficult barrier for meeting study timelines. According to center watch reports 45% of study delays are because of slow patient recruitment and on an average most delays exceed more than six months. Despite the prestudy promise of patients an estimated 30% of study site fail to recruit single subject.

This problem is likely to worsen as number of clinical trials increase in each year and many drugs become more focused, therefore targeting smaller patient pools. In such situations sponsors are contracting the services of patient

recruitment firms to perform a rescue, which involves large sums of money for media campaigns (they require urgent implementation, time and ethical approval process). Many clinical development departments have observed short comings for no proper planning for patient recruitment ahead and rescue modes of approaching patient recruitment firms which may limit the tactics that can be practically employed in a short time frame. Therefore new specialized patient recruitment departments that act as a consultant to their drug development programs are gathering a tool set for patient recruitment a whole suite of solutions.

Patient recruitment solutions

The most common proactive approach to expanding the pool of potential patients (beyond those known to the clinic) involves media campaigns. Adverts for clinical trial participants are placed in a variety of media including local and national newspapers, lifestyle magazines, local radio, clinic leaflets and posters. They may even engage the involvement of community outreach organizations and sometimes include television advertising (although this is rarely employed outside of the US). Interested candidates are directed to a telephone number and/ or website where they can learn more about the study and answer simple questions to determine their qualification for a formal screening visit. Telephone screening can be successfully performed by staff at individual study sites, call centers and using interactive voice response (IVR) systems.

Many pharmaceutical companies have the perception that this style of advertising is unethical or prohibited in numerous countries outside the US, but in fact it is acceptable to both ethics committees and regulators in most countries. Such use of media has the potential to reach large population simultaneously, however, there are usually high costs associated with adverts and their "shelf-life" is very short.

Outreach via the Internet

As Internet usage is rapidly expanding in the present days. The internet therefore represents an expanding community and has great potential for enhancing patient recruitment into clinical trials if applied effectively.

Community – driven approach

Early approaches at patient recruitment using the internet yielded disappointing results. There are billions of websites worldwide: this fact alone can limit the ability of web users to locate a relevant clinical trial opportunity. Banner advertising and pop-up messages irritate web users rather than present them with information of relevance – these are generally ineffective methods of directing traffic to a clinical trial opportunity. Moreover this approach is limited to subset of patients who are actively seeking a clinical trial and ignores those who may be interested if presented with relevant information.

Many web users will seek information about medical conditions and treatments from time to time. Beyond the small subset who actively search for a clinical trail opportunity, the large pool of users represent the target population for a therapy under investigation and specifically for a particular clinical trial. Combing relevant accurate and impartial health care information with education and information about clinical trials in general, and specific clinical trail opportunities, online communities, can engage their audience with regularly updated information and communications enabling long term relationship to be built that enhances the lifestyle of the subject.

Through such communities effective educating and information about clinical trail opportunities can be delivered providing a highly targeted and effective way of reaching out to the target population. The recruitment pool for the clinical trial candidates is a subset of total market or therapy under development. The only differentiators between the population targeted by the therapy and recruitment subset are, a) potential patient knowledge of clinical trial opportunity and b) their willingness to sign informed consent. By developing and using online communities of patients (efficient and focused way) facilitates the widening of pool of target patients who have knowledge of clinical trial opportunity and through education increase their willingness to be a part of such activities.

Few Practical application of community driven web approaches:

- Simple information-rich clustered sites.
- Navigation design.
- Building engagement and trust.
- Building clinical trails candidate database and recruiting subjects

An appropriate use of technology has great promise in enhancing patient recruitment. Pharmaceutical companies are becoming better prepared to include additional patient recruitment activities as part of their prestudy planning and budgeting, using technologies in the above discussed ways provide cost effective and focused approaches that are valuable components of patient recruitment tool kit

Clinical Trials initial Budgets for patient recruitment: Phases of Study

Dr. Sreedhar

Patient optimization, recruitment and retention, a key determinant of the success of a clinical trial, has always been a challenge. It is becoming more challenging with the increased complexity of clinical trial design, stringent eligibility criteria and the trend toward more targeted patient population. Considering importance of patient recruitment & retention in clinical trials to achieve the business objective but surprisingly, many companies do not dedicate any funds to this activity in the initial budgeting process. In fact, many companies do not plan for patient recruitment at all, believing that patient recruitment will happen some companies invest a lump sum to CROs, SMOs or sites and rely on them to recruit patients.

Pharmaceutical companies know that quick enrollment is essential. To aid in the process, some companies employ patient recruitment companies. Others design creative campaigns specifically aimed at the patient set needed for their trials. Whatever their efforts, the companies that support their sites' efforts with good recruitment campaigns, fueled by appropriate budgets, find more success in trial recruitment. This level of support is important because, after all, trial delays lead to product-launch delays which cost money in the long run.

This article en lights on average estimated costs spent by the pharmaceutical companies for patient recruitment for clinical trials from phase I to Phase IV.

Patient Recruitment Budgets

The recruitment pattern for **Phase 1** trials is different as well. One Phase 1 patient enrolled is equal to 10 to 20 Phase 3 patients enrolled. This is partly because of the complications that come along with recruiting patients for Phase 1 trials. After all, the primary goals of Phase 1 trials do not include therapeutic benefit and most often require healthy patients. For Phase 3 studies, doctors will bring in patients one at a time, but for a Phase 1 study, they'll bring in 30 at a time because it's not cost-feasible to do one at a time.

As companies enter **Phase 2** trials, the number of patients required increases, raising the stakes in terms of patient recruitment that overall trial budgets increase for sponsor companies/CROs as well. Along with increases in budgets from Phase 1, the percentage of budgets dedicated to patient recruitment also increases.

Phase 3 trials generally require a much larger number of patients than either Phase 1 or 2 trials. As such, it is not surprising that overall trial budgets increase significantly over the previous two phases.

Phase 4 trials can vary fairly widely in size and scope.

Table 1: Comparison of budgets for patient recruitment at different phases of study

Phase	Over All initial Budget Dedicated for patient recruitment	Per site Budget dedicated for patient	Per patient budget
I	0% and 15%	$10,000 and $800,000	$2,108
II	50%	$5,000 to $90,000	$52
IIIa	50%	$5,000 to $90,000	$60 and $250
IIIb	6%-20%	Higher percentage of their budgets to patient recruitment than 3a	Per patient spend is in line with that of Phase 3a
IV	3%	$12,00	$736

About MakroCare

MakroCare is a global drug development services firm that operates through 4 main divisions - CRO, SMO, Informatics and Consulting. Integrated and innovative services in the areas of regulatory affairs, risk management, site management, patient recruitment, trial management (P II/III and late phase), biometrics, QA audits, PV/Safety, and informatics.