Patient Recruitment: THE PENTAD Of P Model

A Kumar, S K.L, B Kalra, S Kalra

Citation

A Kumar, S K.L, B Kalra, S Kalra. *Patient Recruitment: THE PENTAD Of P Model*. The Internet Journal of Family Practice. 2009 Volume 9 Number 2.

Abstract

Recruitment of subjects in randomized controlled trials is the process of screening and enrolling a predetermined number of subjects within a planned time. To maximize enrollment in the clinical trials, an effective mechanism for screening and recruitment is needed. There are few elements which influence the recruitment process: protocol, personnel from sponsor, patient population and education, physical attributes of site and personnel at site. This paper describes these elements and other crucial information that may be useful in the recruitment of subjects for the clinical trials.

INTRODUCTION

Clinical trials are vital for the advancement of medicine. One factor affecting the success of trials is subject recruitment (1). Recruitment is a vital and integral part of all clinical trials and contributes to both the statistical power and overall success of trial. Additionally, unrepresentative recruitment can yield results that are not generalized to other populations or, more seriously, can result in selection bias due to a "volunteer effect" or diagnostic bias (2). Completion of recruitment on time is essential to complete trials, and generate results on time. Every small delay in recruitment leads to delay in completion, and thus, a financial loss for the sponsor.

There are few elements which influence the recruitment process. These can be listed as a pentad (the five 'Ps')

1. Protocol
2. Personnel from sponsor
3. Patient population & education. Public perception
4. Physical attributes of site
5. Personnel at site
6. Understanding and avoiding common mismatching between the sponsor, protocol, site and prospective subjects will make recruitment easier.
7. Protocol: A clinical protocol is a document that describes the objective(s), design, methodology, statistical considerations, and organization of a clinical trial. The protocol contains a study plan on which the clinical trial is based. The protocol describes, among other things, what type of people may participate in the trial; the schedule of tests, procedure, medicines, and dosages; and the length of the study.
8. Good understanding of a protocol by the site personnel is a must for the speedy recruitment of subjects in a trial. Prior to this, the protocol should be understood at the feasibility stage. It is not uncommon to see investigators standing up at investigator meets to say that they will not be able to perform a particular procedure though it was clearly mentioned in the protocol synopsis
9. Personnel from sponsor/CRO: Sponsor/CRO personnel need to maintain regular communication with the investigator site. Monitor on a daily basis the number of patient recruited, their eligibility, and screen failure and to obtain feedback that will allow them to identify trends and demographic variations in the recruitment process. Rapidly identify and manage poorly recruiting investigator sites, thereby providing the opportunity to cut out poor performers early in the programme and bringing on board back up sites. Identify and respond rapidly to the needs of individual sites and hence adapt and refine the recruitment programme to meet their needs.
10. The sponsor personnel should be friendly yet firm, and try to bring out the best in a site.

11. Patient population and education. Public perception: Patient population for a clinical study depends on the disease prevalence in the surrounding areas of the site. For example, there are good transport facilities in plain areas versus hilly areas, so studies which require frequent followup will have better recruitment in the plains. Diabetes is common in India, and sites in this country have faster recruitment than those in other nations. Access to the appropriate patient population is also important. The investigator should be a treating physician, who should be able to draw on patients from his or her existing practice or a dedicated clinical trialist who sees only research subjects

12. Competing studies may adversely impact recruitment. Existence of any competing trials and their expected dates of completion of enrollment should be enquired into.

13. Patient education also influences the recruitment (3). At present almost all the study design require educated patients. For example, diabetes studies design includes patient's diary for collection of information regarding blood glucose values, and other patient reported outcomes such as quality of life. This means that site with lot of illiterate patients will not be able to recruit subjects as fast as another site with less patients, all of whom are educated.

14. Physical attributes: Recruiting a large number of participants usually requires involvement of a considerable number of centres. However, all centres need to have a patient pool of adequate size, and the infrastructure and resources to recruit and manage the projected numbers of patients efficiently (4).

15. Site experience: Past experience in conducting trials in a similar patient population and assessment of past enrollment performance metrics is important in deciding whether a site can fulfil future targets.

16. Site resources: One should assess personnel resources including the number and type of personnel available, their functional responsibilities, and their relationships to other institutional departments, referring physicians, and community organizations. Financial resources to support hiring and training of additional staff may be needed.

17. Participating research clinics need to be centrally located, easily accessable, well organised, and efficient in scheduling tests, drug dispensing and so on. They should offer flexible appointment times, and sufficient time with the clinical trial staff for participants to adequately understand the study's rationale, its requirements and risks, and have all their questions answered.

18. Site facilities and procedures : Subject-friendly facilities (comfortable waiting room) efficient scheduling; extended clinic hours to accommodate subjects' work schedules, transportation support, subject reimbursement, and compensation amount and procedures will contribute to faster recuitment.

19. Ethics Committee policies and procedures: Ethical review committee attitudes toward patient outreach programs (for example, restrictions on media messages), subject reimbursement should be assessed.

20. Personnel at site: Recruitment depends on appropriate delegation of responsibilities among personnel with sufficient qualifications to perform the protocol procedures involved. Qualification, experiance and motivation are equally essential for successful recuitment.

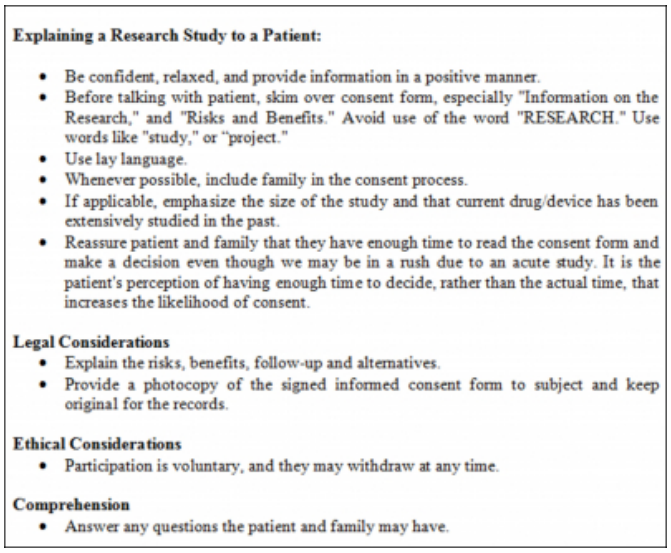
21. Employing an experienced and dedicated research coordinator at each participating centre is a key to successful recruitment, retention, and reduces the time demanded of investigators.

A coordinator should be familiar with all studies to maintain consistency and efficiency. Every coordinator should be able to enroll patients in any study. This policy avoids unnecessary delays in enrollment that occur when a coordinator is unfamiliar with a study and eliminates the frustration of trying to find the appropriate person to answer study-related questions.

CRC should be skilled at verbal communication (in languages) and responding to subjects' questions and concerns. CRC should focus on creating a pleasant

"customer service" experience for the subject. Some key points related to this are listed in Table A.

Figure 1



Explaining a Research Study to a Patient:

- Be confident, relaxed, and provide information in a positive manner.
- Before talking with patient, skim over consent form, especially "Information on the Research," and "Risks and Benefits." Avoid use of the word "RESEARCH." Use words like "study," or "project."
- Use lay language.
- Whenever possible, include family in the consent process.
- If applicable, emphasize the size of the study and that current drug/device has been extensively studied in the past.
- Reassure patient and family that they have enough time to read the consent form and make a decision even though we may be in a rush due to an acute study. It is the patient's perception of having enough time to decide, rather than the actual time, that increases the likelihood of consent.

Legal Considerations

- Explain the risks, benefits, follow-up and alternatives.
- Provide a photocopy of the signed informed consent form to subject and keep original for the records.

Ethical Considerations

- Participation is voluntary, and they may withdraw at any time.

Comprehension

- Answer any questions the patient and family may have.

CONCLUSION

Clinical trial enrolment provides great opportunities for physicians as well as for patients. Patients have access to the newest treatments, and physicians have means of advancing science while cutting costs. Successful recruitment into clinical trials is best achieved by having a feasible recruitment plan, together with dedicated trial staff and adequate resources. Sites with previous clinical research experience can help newer sites to be successful.

The practices described above, may be quite effective in the recruitment of subjects for the clinical trials.

The ''Pentad of P's model'' is a simple method that sponsors and sites can use to assess and monitor subject recruitment.

References

1. Lars-Olof Eriksson, Beth D. Haper. Successful subject recruitment. Applied clinical trials Nov 2002.
2. Phyllis DeSantis, RN, Lee S. Gross, Sue DeLuca. A guide to successfully recruiting patient for cardiovascular clinical trials. Progress in cardiovascular nursing 1997; 12 (3):24-31
3. Debbie J. Daunt. Ethnicity and recruitment rates in clinical research studies. Applied nursing research, vol. 16, No.3, 2003: 189-195
4. Hunninghake DB, Darby CA, Probstfield JL. Recruitment experience in clinical trials: literature summary and annotated bibliography. Control Clin Trials 1987; 8 (suppl): 6S-30S

Author Information

Amit Kumar
AstraZeneca India Pharma Ltd

Sendhil K.L
AstraZeneca India Pharma Ltd

Bharti Kalra
BRIDE

Sanjay Kalra
BRIDE