

# Recruitment and retention of the participants in clinical trials: Challenges and solutions

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## Abstract

Drug development is a tedious and expensive procedure and it takes roughly 10 to 15 years to take a potential treatment from bench to bedside and costs the pharmaceutical companies as much as USD ~2 billion for the process. Delay in investigator-initiated studies can cause financial loss to grant providers (either public or private) and investigator's reputation may also be at stake. Participant recruitment and retention are two major bottlenecks in conducting clinical trials and contribute vastly to the delays. They are essential for both scientific validity of the clinical study and economic reasons. Thus, issues in recruitment and retention should be addressed and minimized. A proper recruitment and retention plan incorporating adequate communication between all stakeholders will eventually avoid the delays in drug development and make treatments available to the consumer at an earlier date and at a more affordable price. Awareness of challenges and reviewing strategies that can optimise recruitment and retention will facilitate drug development. The article gives a first-person perspective on challenges and proposed solutions from an experienced clinical study centre in a tertiary care hospital.

**Keywords:** Clinical studies, nonadherence, recruiting participants, retention

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## INTRODUCTION

“The incidence of patient availability sharply decreases when a clinical trial begins and returns to its original level as soon as the trial is completed”

– Lasagna's Law (1970).

Recruiting the planned sample size within the defined time frame in clinical trials has proven to be the chief bottleneck in the drug development process. It causes missed clinical trial deadlines, leads to increased costs, and consumes more time than any other aspect of clinical

trials.<sup>[1]</sup> Recruitment of participants takes up to 30% of development timelines, and ~1.2 billion USD is spent on this activity.<sup>[2]</sup> Participant recruitment difficulties commonly lead to delays of anywhere from 1 to 6 months for a majority of clinical trials. The remaining experience even longer delays, due to which the pharmaceutical industry stands to lose between USD 600,000 and 8 million for each day of delay. With 11% of clinical research sites failing to enroll even a single participant, and 37% of sites under-enrolling, recruitment strategies must be considered *à priori* and addressed throughout the duration of the study.<sup>[3]</sup>

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Apart from recruitment of participants retention is equally important. Understanding determinants for the lack of retention would help improve it.<sup>[4]</sup> This paper focuses on recruitment and retention of patients/healthy participants in a clinical study, based on our experiences in conducting both regulatory and investigator-initiated clinical research in a tertiary care hospital, and puts forth the challenges and potential solutions to address these aspects.

## RECRUITMENT

### Background

Recruitment in a clinical trial includes the following steps:

1. Identifying or sourcing potential participants who may be eligible
2. Discussing all aspects of the trial with them, ensuring comprehension and voluntariness, and subsequently obtaining informed consent for participation
3. Conducting a physical examination and screening procedures as mentioned in the protocol
4. Enrolling the participant based on the eligibility criteria.

### Narrative literature review

Place of residence, Race/ethnicity/culture/language, Occupation, Gender, Religion, Education, Socioeconomic status, Social capital (PROGRESS) play an important role in clinical trial recruitment and retention. Hence, randomized controlled trials (RCTs) should be integrated with health equity considerations.<sup>[5,6]</sup>

A Harris Interactive Survey done in the UK reported that of patients who were aware of a clinical trial, 71% of the eligible patients opted not to participate.<sup>[7]</sup> Of these 71% of eligible patients, 37% did not participate because the standard treatment was thought to be better, 31% because of fear of receiving a placebo, 22% cited fear of being treated like guinea pigs, and 21% said the distance they would have to travel discouraged them.

A questionnaire-based study conducted among  $n = 73$  investigators across India<sup>[8]</sup> found that frequently encountered challenges in participant recruitment were intricacy of the study protocol (38%), lack of awareness about clinical trials (37%), and sociocultural issues (37%). Additional factors frequently hampering participant recruitment were patient's fear of side effects (33%), negative publicity by media (22%), and large geographical distance from the study site (16.7%). In another Indian study, the respondents felt that signing the consent meant waiving his/her rights to prosecute gives more protection to the doctor/researcher and hospital than to the participant.<sup>[9]</sup>

**Table 1: Common reasons that participants convey for not participating in clinical trials<sup>[6-8,10-15]</sup>**

|   |
|---|
| Intricacy of study protocol                       |
| Sociocultural issues                              |
| Negative publicity by media                       |
| Inconvenient study schedules                      |
| Geographical distance                             |
| Concerns about getting a placebo                  |
| Concern about benefits of investigational product |
| Discouragement by treating physician              |
| Lack of awareness about clinical trials           |
| Fear of adverse events                            |

Table 1 summarizes the most common reasons for nonparticipation in clinical trials.

### Brief about our site

The Department of Clinical Pharmacology at Seth GS Medical College and KEM Hospital, Mumbai, is conducting clinical studies (both investigator-initiated as well as pharmaceutical industry-sponsored) for the past two decades. With a well-equipped three-bedded Phase I unit, biochemistry laboratory, IP management facilities, and a team of DM Clinical Pharmacology residents, Masters and PhD students forming a cohesive unit make it one of the few Phase I units in the country to handle first in human studies.

## CHALLENGES IN RECRUITMENT: A PERSONAL NARRATIVE

1. Healthy participant-related issues
  - a. Age/gender: Healthy participants are often in the active reproductive age and therefore have to use acceptable methods of contraception or even practice sexual abstinence, in some cases, for the entire duration of the study. This becomes a real challenge, especially among the women
  - b. Free medical check-up and laboratory investigations: Many healthy participants tend to use screening tests as a medium to “get a free health checkup” or earn a small amount of money that is given as the compensation for the time and travel for screening. These participants often decline to participate as soon as they get screening test results<sup>[16]</sup>
  - c. Understanding purpose of participation, participant expectations, and situational vulnerability: In our experience, many of these potential participants actually do not listen to or even understand the risks of participation in the trial. When participants who have previously taken part in BA/BE studies come for enrolment in a “first-in-human” study, they often fail to make a distinction between the two. This impacts the risk perception as well as expectation of payment for participation. Participants get a high payment for participation

when they take part in studies conducted at BA/BE Centers and the study duration is short. The study intervention is well known and has a well-established safety profile. The healthy participants who have previously taken part in BA/BE studies often try to “negotiate” remuneration based on what they have previously received and decline participation. A similar experience has been reported by a Hyderabad-based center where they have alluded to existence of a negotiation process on compensation for participation while recruiting healthy participants for BA/BE studies.<sup>[17]</sup>

2. Patient participant-related issues
  - a. Gender: We found that the decision to take part in studies by women was not truly theirs to make (relational autonomy). They had to take permission from their spouse and senior family members or hide their participation from them<sup>[18]</sup>
  - b. Education of the participant: Less-educated patients/healthy volunteers (HVs) needed more time to comprehend and needed longer discussions to allay their fears about audio-visual recording of the consent process [data on file]
  - c. Occupation: Daily-wage earners and some with stable jobs tend to refuse participation in clinical trials involving hospitalization as per the protocol requirements due to concern of losing pay and not getting leave
  - d. Festivals: Patients decline to get enrolled and follow up on festivals and religious holidays. For example, trial recruitment can be slow during Ramadan days in countries with a predominantly Muslim population<sup>[19]</sup>
  - e. Intensive care unit (ICU) fear: Some participants were hesitant to consider taking part in trials because of the fear of the environment of the Phase 1 Unit which resembled an ICU.
3. Sponsor-related issues.
  - a. Protocol: Because of the stringent eligibility criteria, many volunteers were deemed “not-healthy” and resulted in slow recruitment. For example, in a first-in-human study conducted at our site, of the 156 apparently normal participants screened, only less than 50% were randomized. A large pool of male participants screened was excluded because of low hemoglobin (Hb) level (Hb range as per the selection criteria was 13.5–18 g/dl), which was likely to be reflective of their low socioeconomic status, and this impacted recruitment<sup>[16]</sup>
  - b. Laboratory ranges: The standard ranges (normal) mentioned in multicenter studies are often from central laboratories which are quite different from the

“normal ranges” at the site where the study is being conducted. It is possible that the population used by sponsors to define normality can be different from the study site. The use of site-specific reference intervals by sponsors/Contract research organisations (CROs) while conducting multicenter clinical trials could minimize exclusion of a large number of individuals

- c. Investigational Product (IP) management and logistics: Sponsors tend to focus on sites with rapid recruitment and can occasionally request for IP transfer from the slow-recruiting to the fast-recruiting site. This can further delay recruitment at the former site, when they actually have potential participants
- d. Reports: Delays in scheduling, conducting, or receiving reports of a DSMB meeting can impact recruitment
- e. Funds: Slow disbursement of funds by sponsors/CROs leads to delayed recruitment.

## RETENTION

### Background

Retention in a clinical trial is defined as the strategy and tactics designed to keep participants enrolled in clinical trials, from discontinuing participation and dropping out.

A successful participant retention strategy involves:

- a. Treating the participant with respect<sup>[14]</sup>
- b. Being considerate of the participant’s time
- c. Identifying and overcoming barriers to retention in a timely manner.

### Narrative literature review

A survey conducted in the USA which evaluated perspectives of  $n = 1024$  clinical research coordinators on barriers to retention revealed that the length of the clinical trial was the primary determinant (60%) of poor retention with participants’ belief of lack of efficacy of the investigational intervention (43%).

In a research project in which longitudinal studies with  $\geq 200$  participants,  $\geq 80\%$  retention rates over  $\geq 1$  year of follow-up, authors evaluated various retention strategy themes such as contact and scheduling methods, visit characteristics, study personnel, nonfinancial incentives, financial incentives, reminders, special tracking methods, study description, benefits of study, reimbursement, study identity, and community involvement. Authors found out that in such sites – (1) research staff are well-trained, organized, persistent, and communicate well; (2) “Personal touches” matter: tailoring retention strategies to participants helps. The authors also provided an excellent cohort retention toolkit, which contains

tools to help researchers maximize retention of research participants—such as participant contact information form, follow-up protocols, locating participants, communication templates and manuals, as well as staff training.<sup>[20,21]</sup>

Researchers can take help from evidence-based qualitative strategies like the one which the University of Bristol has developed – the QuinteT Recruitment Intervention – which seeks to optimize recruitment and informed consent in RCTs.<sup>[22]</sup> This framework encourages the collection of information to identify recruitment obstacles and facilitate improvements to the recruitment process.

### Challenges in retention: A personal narrative

Being a dedicated clinical research department, our dropout rate has ranged from 3% to 8% in the last 3 years (data on file). We have seen that appropriate/compassionate communication with the participant and establishment of a rapport by the study coordinator with the participant are the two most important reasons for our low drop-out rate. The study staff are trained to anticipate problems early on to enhance adherence to the protocol by the participant and therefore preventing participants from withdrawing from an ongoing trial. The following signs are usually trigger points for us, warning us of imminent dropouts – not picking up calls, switching off cell phones, missing visits, difficulty in contacting participant at his/her address, or repeated complaints about the site visits. Measures are taken to address such signs of potential nonadherence.

Table 2 describes the reasons for participant nonadherence to the study protocol hindering retention.

### PROPOSED SOLUTIONS FOR RECRUITMENT AND RETENTION: A PERSONAL PERSPECTIVE

Having a sound recruitment plan contributes to a large extent in the completion of the study by the participant. Learning from mistakes of previous trials and assigning an experienced clinical research coordinator for recruitment go a long way ensuring good compliance. Conditions dictated by the study protocol and actual patient population, as well as actual time of enrolment at a given site, do differ. Hence, the recruitment plan is usually dynamic and changes through the clinical trial duration. The recruitment

plan will be influenced by where the clinical trial sites are situated, given the differences in adjoining socioeconomic and geopolitical situations.

While creating a recruitment plan, the following things should be considered:

1. Potential participant characteristics – demographics and personal attributes – is the patient educated, is his/her personality compatible with remaining compliant? Adult and pediatric clinical trials need different approaches to recruitment
2. Key influence – patient’s primary reason for participating – is the patient participating for the free medication and investigations, is his/her participation altruistic, to serve humanity, or is it that there is no effective therapy for the condition under study?
3. Barriers to participation – what are the patients’ concerns regarding participation. Is he/she worried about getting time off from work, is he/she worried that he/she may be getting a placebo?
4. Motivators for participation – for example, what would make the patient happy – small items of appreciation, prearranged transport to and from the facility?

### Recruitment and retention strategies

- a. Protocol-making phase: The sponsor should identify and engage all stakeholders as equal partners in the process of protocol writing and ensure the relevance of the scientific question to stakeholders. The sponsor should take inputs from sites for designing a protocol so that the site-related issues in recruitment and retention can be addressed at the level of protocol writing. The protocol should not be too complex so as to turn away potential participants. The eligibility criteria should be pragmatic. Too frequent data collection time points increase the burden on the participant as well as the clinical trial staff. Hence, data collection visits should be planned only as necessary to maintain patient safety and answer the scientific question
- b. Site selection and clinical trial conduct phase: Sponsors should select appropriate sites based on evidence-based trial feasibility analysis, and such sites should have investigator with required experience, adequate site infrastructure and institutional resources, and target population access. A well-conducted site initiation visit by an experienced sponsor representative helps clear the confusion about study-related procedures. Adequate budget should be provided to the site while creating the client trust account and funds should be disbursed in a timely manner so that site staff remains motivated to continue working efficiently for the

**Table 2: Reasons for participant nonadherence (personal experiences)**

|   |
|---|
| Relocation or migration to another place  |
| History of adverse events on participation                                      |
| Fear of study-related procedures  |
| Length of the study   |
| Problems with participants’ employers regarding time off to attend study visits |

- trial. By ensuring realistic recruitment milestones and routine site performance monitoring, recruitment and retention targets can be realistically met
- c. Communicating with potential participants phase: Appropriate communication strategies should be planned and implemented and these impact both recruitment and retention. The use of institutional ethics committee (IEC)-approved recruitment strategies such as newspaper advertisements or social media campaigns will help recruit patients faster. Creating a potential participant database is helpful to expedite the study enrolment. Partnering with local medical associations to inform other colleagues about the trial, placing flyers in their offices, or sending study details to their mailing lists (after obtaining IEC approval for these strategies) will also help
  - d. Other considerations: A central nationwide HV database will help identify and eliminate “professional HVs.”<sup>[23]</sup> It is possible, perhaps, to incorporate the needs of a protocol in the Clinical Trial Management System or hospital management information system<sup>[24]</sup> to filter out and identify ideal patients based on specific criteria as per the protocol and to create lists of eligible potential trial participants who can be approached. Detailed counseling about clinical trials helps minimize therapeutic misconception<sup>[25]</sup> – another strength of our department. Potential participants may be unfamiliar with or wary of clinical research. Explaining a diagnosis, medical procedure, or clinical trial in a friendly, accessible tone will help put patients at ease and increase both recruitment and retention. Patients who feel active and autonomous in their health management are more likely to be compliant patients. Sending reminder calls for follow-up visits, thank you notes, and birthday cards and WhatsApp reminders/giving trial-specific supplies (glucometer for patients in antidiabetic trial, mosquito nets for malaria prevention trial) may help motivate participants to remain in the trial. Informing patients that their contribution is significant to the trial, making help them feel appreciated by PI helps to recruit and retain patients in subsequent trials too
  - e. Adapting latest technologies: There are many innovative start-ups like *Deep 6 AI* which use artificial intelligence and machine learning, to improve recruitment and retention.<sup>[26]</sup> For example, for a trial *Deep 6 AI* took just 1 h to identify 16 potential participants as against the conventional approach that had found only two people in 6 months.<sup>[27]</sup>

**Table 3: Solutions to challenges in recruitment and retention of participants - Personal narrative and literature review<sup>[28,29]</sup>**

| Challenges   | Solutions for recruitment   | Solutions for retention   |
|--|---|---|
| Trial design with stringent eligibility criteria and longer follow-ups | Sponsors and investigators<br>Early sponsor-investigator-other stakeholders’ meetings to draft a pragmatic protocol to address anticipated recruitment issues while writing a protocol<br>Piloting the study in few sites and learn from the experiences  | Sponsors and investigators<br>Setting realistic targets (site recruitment targets, feedback, and competition among sites)<br>Options other than complete withdrawal<br>Patient and public involvement<br>Use of prescreening logs |
| Declining site performance due to insufficient resources               | Sponsors<br>Develop site resources (e.g., giving necessary equipment to ease clinical trial conduct)<br>Dedicated sponsor help desk for queries<br>Disbursing funds to the site in a timely manner<br>Investigators<br>Staff training about recruitment   | Sponsors<br>Develop site resources<br>Staff training about retention  |
| Poor patient contact   | Investigators<br>IEC-approved newsletters, newspaper advertisements, scientific/educational presentations, patient support events, and community engagement, WhatsApp group notifications or other social media<br>Continuing contact with wait listed participants<br>Recruitment reminders (e-mail/CTMS alerts) | Sponsors and investigators<br>Additional contacts (reminders, newsletters, feedback for patients, websites calendars, and alert cards)  |
| Patient inconvenience  |   | Sponsors and investigators<br>Flexible appointments   |
| Nonmotivated site staff or participants                                | Sponsors<br>Incentives (gifts for sites, co-authorship for good recruiters, and monetary incentives)<br>Recognizing site champions<br>Newsletters encouraging good sites  | Sponsors<br>Incentives (gifts for sites, co-authorship for good retention, and monetary incentives)   |
| Other factors  | Investigators<br>Relationships (face-to-face initiation visit, regular contact with recruitment staff, and ongoing relationships between trials)  | Investigators<br>Relationships (support for patient between visits, handwriting envelopes, festival/birthday cards, and thanking participants)  |

CTMS=Clinical Trial Management System, IEC = Institutional Ethics Committee

Table 3 mentions a summary of solutions to challenges in recruitment and retention of participants in a clinical trial.

## CONCLUSIONS

Recruitment and retention of the participants are integral to the success of a study and strategies for optimizing both must be discussed *à priori* and implemented as planned. These strategies must be reviewed and revisited with each new trial to improve recruitment and retention in the future studies. Research in these strategies in the India context will help develop site specific plans which can be made site specific and implemented.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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