

Title

Research Methodology Tip - Subject Recruitment and Retention in Clinical Research: Leading Tips to Get It Right

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Organisation

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Healthcare Administration

Applicable Specialty or Discipline

Clinical Research

Content Category

Training & Education

Learning Theories, Methodologies & Framework

Keywords

Research Methodology, Subject Recruitment, Retention

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Recruiting an adequate number of eligible subjects, and retaining them for the entire study duration specified in the study protocol to ensure complete data collection, is essential for the success of a clinical research study. Failing to do so leads to delays in study deadlines, methodological insufficiency to answer the research question, introduction of unanticipated bias, increased costs, and wastage of valuable resources.

Current literature suggests that well-planned patient-centered strategies which involve continuous engagement of stakeholders have the potential to address the challenges often faced during recruitment and retention. Chhatre et al (2018) developed a conceptual model comprising 4 levels of factors (patient, physician, hospital, and community) that contribute to engagement, recruitment and retention of participants in clinical trials. Trust, attitude, communication, and expectations between patients and physicians/study investigators, are the core concepts of this model (*Figure 1*):¹

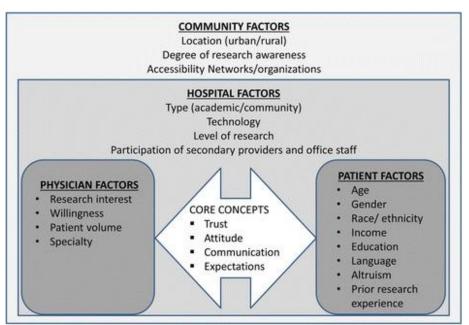


Figure 1. Conceptual model of patient-centered recruitment and retention.

This model also reinforces the idea of understanding patient-level barriers, and addressing their unique needs at the protocol development stage itself, for improved participant recruitment and retention.

Protocol Design Stage

Gather feedback from personnel at recruitment sites (co-investigators, nurses, clinical research coordinators, etc.).

Set pragmatic eligibility criteria for participation, and absolutely necessary followup data collection points pertinent for answering the main scientific question.

Conduct a pilot study before the large-scale trial to understand the barriers.

Recruitment Stage

Contact eligible and interested subjects as soon as possible for screening.

Assess available communication channels for convenience and employ wherever possible.

Detailed counselling on the importance of the research, study procedures and expected time commitment in a friendly, accessible tone.

Record the contact number of a family member and/or a close friend, in case the subject misses a follow-up visit.

Ongoing Retention

Address participants' concerns during followup visits and provide periodic updates on study progress to sustain their interest in the study.

Introduce compensatory incentives, such as taxi fare, gift cards, etc.

Send handwritten thank-you notes, birthday wishes, etc.

In case of missed visits, try to contact multiple times at appropriate times of the day.

Figure 2. Strategies for successful participant recruitment and retention.

Some key strategies for recruitment and retention of participants are highlighted above (*Figure 2*). Additionally, study operations can potentially be further improved by tapping on different channels of communication media and innovations that use artificial intelligence and machine learning techniques, especially in the current era of telemedicine and virtual follow-up.^{2,3} In any study, recruitment and retention are ongoing processes; the strategies for these should be revisited from time to time. In case of delays in recruitment or higher-than-anticipated drop-out rates, the strategies should be reviewed and amended to rectify the problems.

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Resources

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