Customizing patient retention strategies in clinical trials

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Background

- While patient recruitment is often highlighted as the key factor in ensuring study success, the area of patient retention in clinical trials is often overlooked. Retention of patients throughout the life of a clinical trial is however vital from scientific as well as economic point of view. Poor retention negatively impacts on the overall evaluable data for regulatory submissions. Dropped participants must be replaced which incurs further expenditures and time delays. Subject dropout rates are estimated to range from 15-40% of enrolled participants in clinical trials.[1]
- Some reasons for subject dropout are within the control of study staff (such as issues related to convenience) or can be addressed through careful study design. Other reasons are beyond the control of study teams, such as adverse events. Therefore, retention can never reach 100%. [1,2,3]

Patient retention methods and tools available

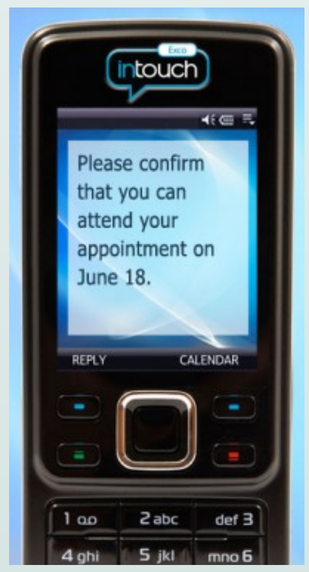
- Educational materials and appreciation of the subject's time and dedication to the study are the two vital principles of patient retention.
  - Educational tools for patients will provide them with a better understanding of the clinical trial process, adequate information about the treatment risks, and advice on how to make the trial more comfortable and convenient.[4]
  - Incentives for patients may typically include some combination of medical treatment and cash compensation, intended to provide for reimbursement of expenses (travel, telephone usage, missed work, babysitter, lunch etc.) but not to be so large that study participants would ignore the risks of participation.[1] Being treated with respect and kept informed will help to make the overall experience of trial participation positive for all subjects.

- Retention starts at the subject's very first visit. The site staff should be prepared to explain the key questions underlying study participation.[5] Once the patient is enrolled, it is important to maintain patient motivation and provide positive reinforcement at every subsequent visit. There are several relatively simple measures which can reduce the likelihood of dropout (Figure 1).

Figure 1. Examples of retention tools and their effects

Retention tool	Consequent effect on retention
Visit planning tool and reminders	Patient can see the actual visit dates based on his trial enrolment date
Calls to patients between visits	Help to address patients concerns, remind of upcoming visits, encourage compliance, ascertain understanding of the given instructions
Availability and responsiveness of sites staff	Patients will feel more secure having 24/7 access to trained study staff
Same site personnel	Will help to facilitate trusting relationship with the patient
Convenient timing of appointments	Will facilitate patient's compliance with the study schedule and prevent missed visits
Educational and support study materials for patients and their families	Will help to communicate the study's values
Appreciation items – e.g. calendars, thank you notes, birthday cards, meal vouchers, rucksacks or bags with study logo	Will help to acknowledge subjects' efforts and time spent on the study

- With developing technology, there are also quite a few innovative techniques emerging in patient retention:
  - Study-specific websites provide a way to maintain contact with patients, offer ongoing support and information, and enable to share personal experiences
  - SMS allow to interact directly with subjects, with customized visit and medication reminders[6]
  - Interactive Voice Response (IVR) is often easier for patients, especially seniors, than using the internet or a palm device[1]



- All patient retention items must be approved according to the relevant local guidelines, as their acceptance varies widely.

Customizing the retention strategies and tools

In order to maximise the success of patient retention strategies applied, it is essential that the methods used are customized to specific situation in each clinical trial. Several key factors affecting the choice of retention strategies used are patient population, therapeutic area, study design, geographical location, and the individual site characteristics. Figure 2 gives further details of these factors and the relevant variables affecting retention tools.

Figure 2. Examples of factors affecting customization of patient retention methods

	Factor				
	Patient population	**Study design**	**Geographical location**	**Site location**	**Therapeutic area**
Examples of variables	Indication Concurrent diseases Concomitant medications Patient's age	Design type – parallel or cross-over Control type – active or placebo Duration of treatment and follow up Number and timing of study visits Methods of assessment	Appropriate retention methods and tools Patient and site incentives Regulatory and ethics guidelines	Individual processes for patient retention Site resources and infrastructure Specific training for site staff	In- or out-patient population Chronic or acute illness Competing trials

Retention plan

Patient retention plan should summarise key retention objectives and present sample templates and resources for all patient retention activities to be used. For larger multinational trials, an overview of country-specific information should be included. Timely preparation of a customized retention plan with input from all key stakeholders will ensure that it is incorporated upfront as part of the overall trial recruitment strategy. Such a plan can be prepared by the sponsor company or by external providers such as CROs or specialist recruitment companies. It is essential to consistently apply strategies highlighted in the plan starting from the very first study visit throughout the whole duration of the trial.

Conclusion

Successful retention of patients throughout the duration of a clinical trial has scientific as well as budgetary implications. There are numerous patient retention methods and tools currently available. It is however vital to customize the patient retention methods for each individual clinical trial based on a number of key decisive factors like the study design, therapeutic area, patient population, geographical location and site characteristics. A customized patient retention plan should be prepared and integrated as a part of the overall trial recruitment strategy.

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