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C H A P T E R

The Importance of Retention

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Objectives

- Discuss the importance and timing of conducting protocol feasibility research with potential Investigators and participants.
 - Detail the challenges subjects may face while remaining enrolled and compliant, providing possible solutions to the challenges.
 - Provide data points for a Recruitment Lessons Learned Database.
 - Review the components of Recruitment and Compliance Kits.
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Introduction

The successful implementation, management and completion of multi-center, global clinical trials depend, in large part, on the timely recruitment of highly compliant and protocol-adhering participants. It is prudent to ensure an edge is given to your study over those of other companies with competing products. That competitive edge could be the level of care and steady flow of educational materials that study participants, their family or caregivers will receive during the course of the study.

When recruiting participants, we sometime lose sight of the endpoint of our efforts: that we only submit *evaluable patient data* to our government regulatory authorities. So it is important to have a plan and a process for not only recruiting and enrolling the required number of subjects, but also ensuring that they follow the protocol regimen, take the medication when they are supposed to and as directed, and that they keep all their office visits.

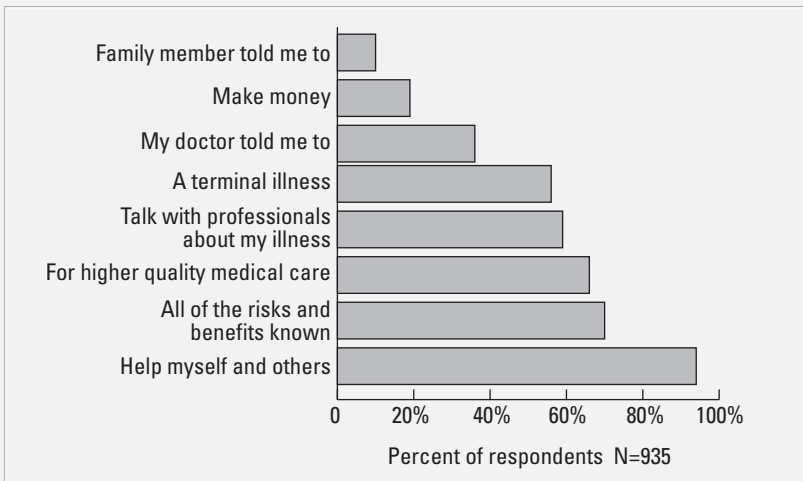
The Participant Adherence and Retention Plan

The Participant Adherence and Retention Plan has to come from a review of historical data from similar studies and from market research focused on the patients most likely to meet the study criteria. In addition, sites should develop a process to identify and screen those potential participants at high risk for non-adherence and study dropout. Sponsors often neglect this phase of the study because they wait too long to plan a combined recruitment and retention strategy or inadequately fund it. Little effort is focused on how the site can keep participants motivated and address their needs throughout the study.

Retention plans are not just for studies that continue over a long period of time. Many studies require frequent site visits or each appointment may last for several hours, placing a burden on the participant, or caregiver. Retention programs are needed for studies with difficult dosing regimens, data collection, invasive procedures, extensive caregiver requirements and unpleasant side effects of the compound. Adherence programs supplement the retention programs by offering guidance on the proper dosing of the medication, the value of staying in the study and the importance of each site visit.

To improve the success of our trial efforts, we must understand many aspects of the participants' lives, medical beliefs, daily habits, moral convictions, disease seasonality and impact of the family on the potential participants. Adherence and retention will have barriers associated with them and they should be addressed.

Table 1: Reasons for Willingness to Participate



Source: CenterWatch, 2002