



METHODS FOR ACHIEVING AND MAINTAINING ADEQUATE STUDY SUBJECT PARTICIPATION FOR A MULTI-SITE TIME-SERIES TRIAL

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We sought to collect data from a national sample of adults in the United States seeking opioid dependence treatment in an outpatient setting. From among a pool of several thousand physicians listed on a national registry, we secured agreements with more than 450 practices to invite their patients to join the study. Within three months, we successfully enrolled more than 2000 patients through their private physicians into the study. Subjects were required to complete a 10-15 minute baseline telephonic interview and four additional 15-30 minute telephonic interviews throughout the six month study. A variety of methods were used to maximize study enrollment and to retain subjects over the course of six months. Coordination of multiple patient and physician touch points was required. Not only were physicians asked to attend training and distribute study materials to patients, they were also asked to collect informed consent forms from patients. Because inclusion criteria dictated that patients must be new to treatment for opioid dependence, collection of baseline data had to coincide with treatment start. It was critical that any patients interested in joining the study and who provided informed consent be contacted immediately so that baseline data could be gathered. Techniques for patient engagement included remuneration for completion of each telephonic survey in addition to an incentive for enrollment. Baseline and follow-up interviews were scheduled according to subjects' preferences. Patients also received study updates in the mail and through their personal physicians. Over the course of six months, the subject retention rate is at least 70%. We attribute this to a number of strategies, especially an efficient study enrollment process, well-managed study administration, and consistent communications with both patients and physicians. Researchers recruiting subjects from a general, treatment-seeking population can achieve sufficient study retention by employing these straightforward methods.