



Compliance and Retention Case Study

Project Synopsis

A major pharmaceutical company was having challenges keeping patients retained during a seven month, seven visit study. Patients were forgetting to fill out their diaries and many were dropping out or were lost to follow up. The drop out rate was close to 50%. The study needed 500 subjects to complete enrollment.

Project Approach

A compliance plan was developed to keep the patient interested in the study and enforce the importance of filling out the study diary. A retention program was also developed to decrease the drop out rate by reminding the patient of their next study evaluation visit at the site and their importance to this study.

Project Plan

The Compliance Program was comprised of multiple tactics to support the diary compliance goals. First, a website was developed to provide study subjects information about the study, their illness and provide a venue to share personal experiences with others with the trial. Weekly emails and monthly letters were sent to enrolled subjects that had specific messages depending on their progress within the study.

Two tactics were used to increase the retention rate for this study. One week prior to each study visit, an outbound call was made to the study subject to remind them of their scheduled visit and other visit information, if necessary (for example bringing medication lists). Once they completed the study visit, the study coordinator gave them an “appreciation” gift and appointment reminder card for their next visit.

Project Results

As a result of the Compliance and Retention programs, the rate of dropouts was nearly cut in half.

Conclusion

- The cost of these retention and compliance programs was \$76,000
- This study was completed **four months earlier** than previously forecasted with the high dropout rate
- The cost to obtain and support a completed study subject averaged about \$12,000. By decreasing the drop out rate, the sponsor realized over **\$780,000 in savings** by not having to identify more study subjects to replace those who had dropped out

Retention and compliance is just as important as enrolling patients into the trial. By planning and budgeting these programs in advance, timelines and budgets can be minimized.