

## Measuring Site Performance with Subject Feedback

By Norman M. Goldfarb and Werner Huck

Dedicated clinical research sites, unlike medical centers and physician offices, focus entirely on clinical research. Their success and even survival thus depends on high rates of customer – sponsor and subject – satisfaction.

Advanced Clinical Research (ACR) is one of the first free-standing clinical research centers in the Rocky Mountain States. It employs 13 study coordinators and approximately 100 part-time investigators at four centers in Utah and Idaho. In 2005, it enrolled over 500 subjects in 45 clinical trials.

Like businesses in many other industries, ACR obtains customer feedback in a systematic manner. This article discusses its subject feedback program.

At his/her final study visit, ACR asks each subject to complete a one-page questionnaire. On average, 63% of subjects complete and return the questionnaire. Although subjects have the option to mail in the questionnaire and remain anonymous, 85% elect to identify themselves. Among other questions, the form asks subjects to rate their study experience on a scale of one (poor service) to ten (excellent service) for the following criteria:

- The initial explanation of my participation in the study
- The clarity of the consent form I signed
- The study personnel's accommodation in setting up appointment times
- Overall interaction with the study personnel
- Overall interaction with the Doctor and staff
- Monetary compensation for my participation
- My overall rating of the study

The authors have analyzed feedback data from 2,043 subjects collected over an 11-year period ending in 2005.

Table 1 presents the average scores and the scores less than 6.0, as a measure of relative dissatisfaction:

**Table 1. Feedback Scores**

Criteria	Average	Scores <6.0
The initial explanation of my participation in the study	9.4	0.8%
The clarity of the consent form I signed	9.3	0.7%
The study personnel's accommodation in setting up appointment times	9.7	0.9%
Overall interaction with the study personnel	9.6	1.1%
Overall interaction with the Doctor and staff	9.5	1.7%
Monetary compensation for my participation	9.2	3.9%
My overall rating of the study	9.4	1.2%

The ACR study experience scored very high on all criteria: 40% of subjects gave a perfect score, while only 1 subject gave it an overall rating less than 5.00. Nevertheless, there are some variations across criteria. "Monetary compensation for my participation" stands out as the criterion with the most issues. Some dissatisfaction with stipends is not surprising and it is unclear whether higher stipends would help. The distant runner-up for issues is "Overall interaction with the Doctor and staff." The leading cause for this complaint is excess time waiting to be seen by the investigator or clinic staff.

There are four primary ways to improve subject satisfaction scores:

- Improve performance.
- Set realistic expectations.
- Influence attitudes, e.g., with personal relationships.
- Select a population that tends to give higher scores.

Improving performance and setting realistic expectations are obviously beneficial. Influencing the scores can be done the right way – e.g., by empowering the subject – or the wrong way – with threats. Screening out potential -subjects who are likely to be dissatisfied is advantageous to both parties.

The questionnaire also provides space for comments. ACR received both praise and complaints. Most of the complaints fell into four categories:

- I was misinformed, e.g., study was more work than expected.
- I was treated unfairly, e.g., not paid for an extra visit.
- I was treated disrespectfully, e.g., the investigator was curt.
- My health did not improve.

Not every complaint, e.g., the last, can be addressed with better performance. All, however, can be addressed by setting and maintaining realistic expectations, and creating strong interpersonal relationships.

Identifying and remedying issues as they arise will yield a better result at the end; in fact, retail customers who have complaints that are satisfactorily addressed are more loyal than customers who never have complaints. The same principle probably applies to study subjects.

Subject feedback can be used for many purposes:

- Identify and correct problems with specific subjects.
- Improve satisfaction merely by requesting feedback.
- Increase re-enrollment rates.
- Identify and correct problems with specific site personnel, specific functions, or with the site as a whole.
- Continuously improve service quality, even from a high level.
- Increase enrollment in future studies.
- Support marketing claims.
- Support compensation programs.
- Track satisfaction and community attitudes about research participation over time.

Given how difficult it is to recruit subjects for clinical trials, it is well worth the effort to ensure satisfied "customers" and positive word-of-mouth.

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