

Systematic Customer Service for Clinical Research Sites

By Norman M. Goldfarb

Academia's share of industry-sponsored clinical research declined from 80% in 1991 to 26% in 2004, in part because it takes academic sites so long to negotiate clinical trial agreements and obtain local IRB approval.¹ In business terms, the service providers did not meet the customers' needs, so the customers went elsewhere.

As measured by filings of FDA Form 1572 – Statement of Investigator, the U.S. share of industry-sponsored clinical research has declined from 76% in 2002 to 56% in 2006.² In other words, U.S. sites have lost over one-quarter of their share of the market in a mere four years.

Numerous countries in both the developed and developing world have gained market share. However, the most rapid growth has been in developing countries such as Russia, Argentina, India and China. U.S. sites cannot compete with these countries on price or the availability of treatment-naive patients. Data quality (as measured by query rates) is just so-so in the U.S.³ The U.S. has no sustainable advantage in clinical trial technology such as electronic data capture (EDC), interactive voice response (IVR), or clinical trial management systems (CTMS).

U.S. sites do have some advantages, such as:

- Numerous experienced and skilled investigators and study coordinators
- Advanced sponsor and service-provider infrastructure for site monitoring, central labs, etc.
- Advanced human subjects protection infrastructure
- Advanced medical training and healthcare infrastructure
- Advanced general infrastructure (e.g., telecommunications and transportation)
- Mature regulatory environment
- FDA preference that NDA applications include at least some trials in the U.S.
- Diverse genetics, ethnicities, lifestyles and environments (e.g., light-skinned Caucasians in sunny Arizona)
- Predominant share of key opinion leaders
- Physical proximity to U.S. sponsors

These advantages are probably adequate to support U.S. market share at about half the current level. However, if U.S. sites want more than 25-30% of the market, they need to follow the lead of many other industries and rethink how they do business.

The three primary competitive dimensions are price, quality and delivery. U.S. sites cannot compete on price or delivery (enrollment). They are already losing the battle of quality as measured by query rates. However, quality can be defined more broadly to include service. Many U.S. companies successfully compete with low-cost foreign producers by emphasizing high-quality service. Customers in many markets pay a premium for service, especially in service industries. Nordstrom and Washington Mutual Bank are examples in retail and banking, respectively.

Clinical research is a service industry. Investigators and study coordinators leap through fire every day to complete studies, but there is seldom a systematic approach to customer

service. Without a systematic approach, customer service will be inconsistent and focused on the crisis du jour.

Systematic Customer Service

Systematic customer service requires stepping back from the emergency of the moment and asking, "How can we please our customers consistently over the long term?" It requires a commitment to understanding the customer's point of view, identifying and addressing service problems, and communicating with customers.

An effective program of systematic customer service includes these elements:

- Relationships with customers wherein they are comfortable discussing service issues.
- Methods to identify service problems and opportunities.
- A system for measuring service levels and perceptions over time.

If you do not have systematic customer service, you probably do not know:

- How to measure the satisfaction level of your customers
- How satisfied your customers are with your service
- Your customers' top five negative perceptions of the service you provide
- Your customers' top five positive perceptions of the service you provide
- How these negative and positive perceptions have changed over time
- How your customers perceive your site vs. other sites
- How you are going to improve your customer service over the next year, and how you expect the changes to improve customer satisfaction
- How changes in customer satisfaction affect your revenue, profits and employee productivity and morale

Communicating with customers is fundamental to systematic customer service.

Communication can be structured, e.g., specific questions that are asked at the end of each site monitoring visit. It can be unstructured, e.g., in informal conversations. It can be indirect, e.g., through back-channels. It can be deductive, i.e., deducing customer attitudes based on their statements, actions, tone of voice, and body language. All of this information can be collected and organized to detect informative patterns and changes over time.

Complaints play a special role in customer service. In general, customers complain only if they want you to improve your service for their future use. In that sense, complaints are a vote of confidence. Seldom are complaints good news, but they do identify problems that can then be addressed. They also provide opportunities to demonstrate superior customer service and win customer loyalty.

Unfortunately, in clinical research, the customers (sponsors) tend not to complain; they just move on to another site (or country). That means other ways to identify sources of dissatisfaction become more important. Asking for constructive feedback is an obvious approach, especially in the context of a systematic program that suggests the request is sincere and there will be no negative repercussions. "Reading between the lines" is another.

Metrics play a key role in systematic customer service. There are two types of metrics: those that measure service performance, e.g., data query rates and time to submit regulatory packages, and those that measure customer satisfaction itself, e.g., "on a scale of 1 to 10, how do you rate our customer service?" The absolute numbers are informative, e.g., a 10 on a 1-to-10 scale is either very good or very bad news. Comparing metrics across studies, sponsors and time eliminates the effect of biases that are introduced, for

example, when customers are uncomfortable speaking openly. The data may be biased, but, if there are 10 questions in a satisfaction survey, you can still identify which are your strongest points and which the weakest.

Once baseline levels of service performance and satisfaction are established, you can identify areas for improvement. You can set goals and priorities for improving the metrics. Over time, service will improve, customer satisfaction will increase, and your organization will gain competence in the improvement process itself. A systematic customer service program and the metrics it generates will become selling points for your research site. Customers will become more satisfied and helpful because they know you care about customer satisfaction and are doing something to improve it.

Conclusion

U.S. research sites are fighting major trends in the market. In five years, many will disappear. Project managers, clinical research associates, and other U.S.-based sponsor personnel will also disappear. U.S. sites that want to continue conducting clinical research would be wise to please their customers. U.S.-based project managers, etc. who want to keep their jobs would be wise to help them learn how to do it. Research sites in developing countries can get ahead of the curve by adopting the same practices to deliver more value to their customers.

References

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