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Reinventing the Site Questionnaire

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In a typical study, 20-25% of research sites enroll zero subjects. Most of the rest do not meet their enrollment commitment. Enrollment is not just an essential component of study conduct; it is also a proxy for other components. From this abysmal performance, we can conclude that there is an opportunity to improve the process for selecting sites. The best solution is to establish long-term relationships with high-performing sites. However, to identify new sites, site questionnaires will continue to play a central role.

Site questionnaires, typically one to two pages long, include a variety of questions intended to help sponsors identify sites that are likely to be successful in a study. Current site questionnaires, such as the one in Figure 1, may give sites the impression that the sponsor is not sincerely interested in accurate responses, or in the site as a valued partner. As a result, many sites return the questionnaires late or never, or provide inaccurate or incomplete information. A recently published study determined that, of 19 questions commonly found in site questionnaires, none – zero – had statistical significance ($p < 0.05$) in predicting enrollment.[1]

The current process may give inexperienced sites the impression that if the sponsor reviews their questionnaire and accepts them into the study, they belong in the study. More experienced sites understand that the purpose of the questionnaire, from the site's perspective, is to obtain an invitation to the study, at which time the site can look more closely at the study's feasibility and decide whether or not to accept the invitation. Either way, the interests of the sponsor are not well-served.

Perhaps sponsors could improve the site questionnaire process to increase return rates, timeliness and data quality. It would be useful to ask research sites to critique the forms and suggest improvements, such as:

- Redesign the form to provide necessary information, ask unambiguous questions, provide adequate space for answers, and limit the questions to essential and non-redundant information.
- Provide the form as an online questionnaire.
- Pre-fill the form with information the site has provided for previous studies.
- Give sites visibility on the status of the selection process.

In designing site questionnaires, sponsors may be asking the wrong question:

> "What information do I, the sponsor, need to select sites?"

A better question might be:

> "What information do we, the site and sponsor, need to decide whether this study is a good fit for this site?"

If the sponsor designs and presents the questionnaire as a way to help sites think through the suitability of the study for the site, rather than the suitability of the site for the study, sites may take more care in completing the information. The information on the form will change in important ways. For example, rather than listing the last three years of studies, it might be more useful to review the last three studies that were most similar to the

Figure 1. Site Questionnaire Example
(Commentary in red)

Add return fax information
so cover sheet is not required.

Phase III Study Opportunity
Osteoarthritis of the [redacted] [Study ID#]
Due: January [day], 2007

PI Name: _____
Specialty: _____
Site Name: _____ Why the short lines?
City, State: _____

1. How many patients with mild to moderate pain associated with osteoarthritis of the [redacted] are currently in your practice?	# of pts: _____ Define "currently"
2. Would you be able to enroll approximately 25-30 patients in 6 months? (a) Of what % would be coming from your practice? (b) Of what % would be coming from local advertisement? No information about the study has been provided. Advertising budget?	☐ Yes ☐ No Other recruiting methods OK? _____% practice _____% advertisement
3. If you're not able to enroll 25-30 patients in 6 months, how many could you enroll? Over how many months? Starting when?	_____ pts over _____ months
4. Do you have full time research coordinators currently on staff? If yes, how many?	☐ Yes, how many? _____ ☐ No

5. In the table below, please describe the PI's clinical trial experience, within the last three years as either a PI or Sub-I. (attach a separate sheet, if necessary) For a busy investigator, this is a lot of information.

Type of study (eg: OA)	PI or Sub-I	Enrollment End Date	# of pts contracted to enroll	# of pts actually enrolled	Length of Enrollment (months)	Type of pt (eg: mild/mod pain)
						Include only pain studies?

5. How many trials has the PI conducted that have used a topical or transdermal product?	_____
6. Do you have any competing trials during the study time period? Competing sites? Start date?	☐ Yes ☐ No
7. Can you use a central IRB?	☐ Yes ☐ No
8. Is the PI willing to participate in an investigator's meeting in June 2007? Dates? Duration?	☐ Yes ☐ No
9. Are you interested in participating in this study, and do you have the available resources to conduct this study during the time period required? What resources? Starting when?	☐ Yes ☐ No
How about: "If yes, please provide name, phone number and email." 10: If yes, please provide contact information. (please include name, phone number and email) For investigator or person completing form?	Name: _____ Phone #: _____ Again with the short lines? E-mail: _____

[Study sponsor's name and study ID number]

proposed study. There might be an online tool for predicting enrollment based on these previous studies, changes in patient populations, and the availability of new treatments.

If would be productive for sites to spend an hour or two reviewing charts for potential subjects. This review will identify problematic exclusion criteria that the site may overlook in the current process. Sponsors could compensate sites for their time, but even without compensation, it is a useful exercise for sites prior to making a firm commitment to a study.

Once a site signs a clinical trial agreement, the sponsor normally never discusses the questionnaire with the site again. Without a comparison of predicted vs. actual enrollment, there is no learning, and no motivation for sites to improve. By reviewing the results internally, the sponsor can develop adjustment factors for specific sites, types of sites, and types of studies. It can conduct experiments wherein it sends one version of the questionnaire to half the sites and another version to the other half. By changing a single feature of the questionnaire in each experiment, it can refine the questionnaires over time. At the bottom of the questionnaire, it can also ask a question about the questionnaire itself, e.g., “How can we improve this questionnaire?

Reference

1. “How Effective are Site Questionnaires in Predicting Site Performance?”, Sherry Reuter and Gretchen Esche, Journal of Clinical Research Best Practices, April 2007

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