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Site Qualification Questions

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Study sponsors and CROs use site qualification visits (SQVs) to assess the suitability of clinical research sites for studies. In a typical SQV, a clinical research associate (CRA) visits the site, interviews the investigator, study coordinator, and perhaps other personnel, and tours the facility. The CRA then completes a form that summarizes the collected information, adds summary comments, and submits the form as a report for consideration by the study team.

SQVs are most productive when the site provides unvarnished answers. However, since the site's normal objective during an SQV is to obtain the CRA's positive recommendation, it is natural for sites to attempt to answer questions in a manner that will meet the CRA's criteria. The site thus attempts to read between the lines of the CRA's questions while the CRA attempts to read between the lines of the site's answers.

In the least effective SQV, the CRA runs down a checklist, asking the site questions like, "Do you have SOPs?" After a few SQVs of this type, sites learn to answer, "Yes, would you like to see them?" If the CRA is on a tight schedule, he or she might not have time to see them or might take a very cursory look to verify that a binder labeled "SOPs" actually exists.

Once all the boxes on the checklist are checked, the CRA departs and submits a report that assures the study team that the site did, in fact, answer all the questions satisfactorily. However, the CRA might have learned very little about the actual capabilities and enthusiasm of the site.

An effective SQV takes longer because the CRA probes deeper in two ways:

- Reviewing documents for evidence that the site is conducting trials correctly. For example, a real set of SOPs will show signs of periodic review and updating.
- Asking follow-up questions that the site is not expecting, like, "What SOPs do you plan to add this year?" or "What can you tell me about the last SOP training session?"

Rather than running down a checklist, the CRA can lead an informal discussion that seems less like an exam, covers important issues indirectly, and puts the site at ease. (The CRA should then review the checklist to make sure all topics have been covered.) In such a discussion, initial questions like "Do you have SOPs?" can be skipped and replaced with questions like, "Do you ever deviate from your informed consent SOP?" The site might assume that the CRA wants to hear "no" for the answer, but a better answer would be, "We try not to, but sometimes we have to. For example, we normally give patients the consent form to read and then answer their questions, but last week a patient started asking so many questions before reading the consent form that we basically reversed the process." This answer demonstrates the site's experience, sophistication and openness. It also gives the CRA the opportunity to give positive feedback to the site like: "Makes sense to me, good thinking."

Table 1 compares questions with obvious answers to questions that might be more revealing. Note that each sponsor and CRO should develop its own collection of questions from which the CRA can draw for an SQV. CRAs can, of course, prepare their own questions or invent them on the fly.

Table 1. Sample Questions to Ask Investigators

Obvious Questions	Revealing Questions
How many years of experience do you have conducting studies?	Have you ever been a subinvestigator?
Have you ever been audited by a study sponsor?	What do you think of the sponsor audit experience?
How many studies are you currently conducting?	What visits are on this week's calendar for all studies?
Do you understand your responsibilities?	What do you think of the FDA guidance on investigator responsibilities?
Do your coordinators have adequate time for a new study?	Can you show me how you track your coordinators' time and productivity?
Do you have SOPs?	Do you ever deviate from your informed consent SOP?
Is there regular maintenance on your equipment?	Can you show me the manufacturer's maintenance guidelines for your minus-80 freezer?
Do you expect any problems recruiting for this study?	Which risks in the investigator's brochure do you think might stall enrollment?
Do you have a full-time study coordinator?	How does your study coordinator split his or her time?
Have you used EDC systems before?	What do you think of the different EDC systems?
Do you regularly monitor ambient temperature in the drug storage room?	What do you do when someone forgets to update the temperature log in the drug storage room?

Although it is time-consuming, CRAs should interview personnel separately to better determine who knows what and check for consistency in the answers. Also, one member of the site's staff might provide less optimistic answers than another member of the staff.

If the site, for example, asks about challenges in a study, the CRA should give an open and honest answer, just as he or she expects from the site.

If the sponsor or CRO has conducted an SQV at the site previously, the CRA should review the previous reports and skip some questions to allow time to explore other areas in greater detail.

Conclusion

The SQV is an opportunity for sponsors/CROs and sites to share information and, perhaps more importantly, begin building a constructive and trusting relationship that will endure over the long term. By moving from a checklist of obvious questions — an IQ test, really — to an informal discussion, CRAs can achieve this objective.

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