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Rehearsing Sites for Successful Study Conduct

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Clinical studies can get off to a rocky start when sites:

- Learn they cannot enroll the number of subjects they thought they could enroll.
- Enroll ineligible subjects or do not enroll eligible subjects.
- Stumble through study visits with initial study subject(s), while working out the procedures and logistics.

These problems are more likely to occur if the study sponsor has not anticipated the challenges of a study: The eligibility criteria might be unclear, the protocol ambiguous, the schedule of events unrealistic, the target population uninterested, or the technology unreliable. The study sponsor should address these issues before the study starts, but it is unrealistic to expect that all problems will be anticipated.

The EKG Incident

Study kits often include EKG leads. After administering an EKG to the first subject in a study some years ago, we removed the first lead. The subject yelped with pain.

As it turns out, EKG leads come in two varieties: one for single use that is easy to peel off and one for multiple use that is not so easy to peel off. The study coordinator had not noticed that the study kit included the multi-use type.

Some sites probably made the same mistake with their initial subjects. Other sites might not have realized they could use different leads.

A Solution

Theatre companies rehearse, dance companies rehearse, orchestras rehearse. Actual lives are seldom at stake in the performing arts, but they are in clinical research. An effective approach to addressing the unknown issues at the beginning of a study is thus to rehearse enrolling subjects and conducting study visits prior to beginning the real study.

Sites can rehearse in the following ways.

- Determine the eligibility of "paper subjects" created by the study sponsor. Study sponsors can tailor medical charts of hypothetical subjects for very specific purposes. Eligibility assessment rehearsals can be conducted at the investigator meeting, the site initiation visit, or other times.
- Review charts to determine the eligibility of patients from the site's database. With this approach, sites can start examining real people for eligibility.
- Contact potential subjects for their interest in participating in the study, should the site ask them to participate. Since the site does not actually ask potential subjects to participate, their interest is only hypothetical.
- Rehearse with "mock subjects" who are not actual subjects. Study sponsors can prepare site monitors to play the study subject role, sites can use their own personnel, or sites can enlist actual patients (with the understanding that the site is just practicing). Rehearsals can be conducted at the investigator meeting, the site initiation visit, or other times. This approach can be fairly realistic, but might not expose unanticipated problems.

- Enroll actual study subjects for an initial assessment period before the real study begins. This approach is entirely realistic but is not suitable for many studies.
- Enroll actual subjects with a clear understanding that the site wants their help in working out potential flaws in the study. It seems only right to give the initial subjects fair warning. This approach should be followed for most studies.

In general, moving from paper subjects to role-playing to real subjects increases realism, reduces standardization, and increases cost and time. Working with paper subjects enables sponsors to quickly detect a defined list of problems at sites. Working with live subjects at multiple sites exposes a wider range of potential problems, but also increases the difficulty of detecting the problems. A combination of methods, tailored for each study, is probably ideal.

Conclusion

The best time to ensure accurate subject enrollment and study conduct is before sites start enrolling actual subjects. In addition to saving everyone's time and effort, it reduces the risk of study delays, avoids unusable or misleading data, and eliminates potential harm to ineligible subjects. When the study sponsor identifies a problem experienced by any site, it can address the problem at that site and share the problem — and solution — with other sites that might see the same problem.

Preparing sites with lectures at investigator meetings, followed by a review of the same material at site initiation visits, provides a training baseline, but does not address many of the problems that are likely to occur during the study, especially before the sponsor and sites have gained experience with the study.

By using one or more rehearsal methods, sponsors can quickly identify problems and train sites to solve them.

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