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Sponsor Report Cards

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Background: Site Report Cards

Many study sponsors provide performance data to study sites in the form of "report cards." Report cards can help sites identify areas of strength and weakness, and motivate them to perform better on a study. Sponsors can also use the data in selecting sites for future studies. In the case of multicenter sites, sponsors can show sites how their performance compares to other sites in the study.

Ideally, report card metrics are selected and calculated in a manner that is useful for both sites and sponsors. For example, if it took a site 93 days to sign the clinical trial agreement, 90 of those days might have passed waiting for the sponsor. A site that enrolled 10 subjects appears to compare poorly against sites that enrolled 20 subjects. However, the site looks a lot better if it joined the study late, with an enrollment target of only five subjects, when the other sites are missing their targets of 50 subjects. Although it might not be possible for sponsors to provide completely useful and self-explanatory data to sites, they can certainly explain how the data was calculated, its limitations, and how it can be interpreted.

Sponsor Report Cards

Just as sponsors can provide report cards to sites, sites can provide report cards to sponsors for each study, or at least compile the data for the sites' own use in future studies. A sponsor that wants to build strong relationships with sites and improve its own performance can ask sites to provide anonymized report cards on the sponsor's performance. By starting to collect this data during a study, sponsors can address problems as they emerge. Sponsors can also assess their own performance and review trends in the data.

Sites can rate sponsors on the following performance elements, on a scale of 1 to 5, with explanatory comments:

1. Site monitors are competent, knowledgeable, professional, reliable, accessible and generally easy to work with.
2. Site monitor turnover is not excessive.
3. Sponsor personnel (other than site monitors) are competent, knowledgeable, professional, accessible, reliable and generally easy to work with.
4. Third-party service providers (e.g., CROs) are competent, knowledgeable, professional, reliable, accessible and generally easy to work with.
5. The protocol (subject recruiting, visit schedule, assessments, etc.) is comprehensive, realistic and practical to conduct. (Sites should evaluate protocols before accepting studies.)
6. The protocol is appealing to, and respectful of, study subjects.
7. The study start-up process (investigator meeting, regulatory, contract and budget) is timely, efficient, straightforward and well organized.
8. The study process after start-up is timely, efficient, straightforward and well organized.

9. The protocol, informed consent form, and other study materials are clear, complete and provided in a timely manner without later, avoidable amendments.
10. The sponsor provides informative and accessible training for the study that is appropriate to the site's needs.
11. The sponsor provides good support (materials, market research, centralized services, funding) for subject recruiting.
12. Electronic systems (IVRS, EDC, etc.) supplied by the sponsor are available, reliable, efficient and easy to use (with good training and clear instructions).
13. Equipment (EKG, etc.) supplied by the sponsor is available, reliable, efficient and easy to use (with good training and clear instructions).
14. Study drug/device is available in the right quantity and at the right time, and easy to reorder.
15. Study kits are complete, available in the right quantity and at the right time, and easy to reorder.
16. Reporting and administrative requirements (screening logs, etc.) are clear and reasonable.
17. Data queries are clear, non-trivial, non-redundant and allow adequate time to respond.
18. The sponsor's proposed study budget is reasonable for the work required.
19. Payments are frequent (e.g., monthly) and timely, with a process that is not burdensome.
20. The sponsor has an appropriate level of concern for regulatory compliance, being neither lax nor punctilious.
21. The sponsor listens to site feedback and requests and accommodates them, when appropriate.

The statements above are intentionally broad and subject to interpretation because more specific statements would require much more detail and a much longer list. Also, broadly worded statements can elicit unanticipated responses. Comments are very helpful in explaining scores. MAGI's standard form for sponsor report cards can be found at http://www.magiworld.org/standards.

Report cards should be completed, evaluated and communicated after a study in a timely manner, while the study is still fresh in everyone's minds, and perhaps at one or points during a study.

Conclusion

Clinical research is designed to advance generalizable knowledge about medical treatments. It should also advance generalizable knowledge about how to conduct clinical research itself. Report cards are powerful tools for accomplishing this objective.

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