Attributes of Exemplary Research

Part 2: Implementing Clinical Trials: A Review of the Attributes of Exemplary Clinical Trial Sites

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At the 2010 ASCO Annual Meeting, members from the Exemplary Attributes Working Group presented an education session regarding the implementation of clinical trials at community-based sites. On the basis of the positive feedback from this presentation, the session faculty agreed to review their content in a two-part article published in the *Journal of Oncology Practice* series on attributes of exemplary clinical trial sites.

The two articles that evolved from the ASCO Annual Meeting session focus specifically on the seven exemplary attributes, as articulated in the statement published by ASCO in 2008. The first of the two articles, published in November 2010, reviewed four of the exemplary attributes: diversification of the clinical trial mix, high accrual activity, participation in the clinical trial development process, and maintenance of high educational standards. This second article focuses on the remaining three exemplary attributes: quality assurance, multidisciplinary involvement in the clinical trial process, and clinical trials awareness programs. Both articles provide practical advice regarding how to implement these attributes in a community setting.

For additional information, we invite you to view a recording of the ASCO Annual Meeting session entitled, *Implementing Clinical Trials: Risks, Benefits, Marketing, and Paying for It All,* via the ASCO Virtual Meeting Web site: http://www.asco.org/virtualmeeting. Because of space limitations, much of the content discussed during the annual meeting session had to be omitted from the articles but is captured in the online recording.

Quality Assurance

Maintaining a quality research program is of utmost importance for a site that conducts clinical research. Implementation of a quality assurance program helps a research site verify that the program is performing at its ideal capacity and adhering to good clinical practice guidelines. This process also helps the research team verify that they are generating high-quality data and recruiting patients who appropriately meet trial eligibility criteria. A quality assurance program is an important investment for a research site because it encourages routine program and research team evaluation to determine areas of both strength and weakness.

There are several mechanisms that can be incorporated into a quality assurance program. Most sites use a variety of these mechanisms and adapt them on the basis of specific needs of the research site. Many sites conduct random chart reviews to verify that clinical trials are being appropriately conducted (ie, all documents are appropriately signed, institutional review board approvals are current, and treatment protocols are rigidly followed). Sites often involve each member of the team in the chart review process or designate one individual to conduct this task and report back to the team. Chart audits provide an important learning opportunity and help maintain the quality of the research program.

Many research programs also institute policies for corrective action when a weakness is identified via the chart review process. Corrective action plans ensure that any identified problems are appropriately addressed in a timely manner. The corrective action plan should help the team learn from the error, thus preventing similar mistakes in the future. Instituting a strict policy for recording major and minor violations is a useful quality assurance technique that helps the team track transgressions and evaluate when corrective action is necessary. A corrective action plan is also a good way to document to sponsors and regulators that the site is being proactive about maintaining quality.

Another component of a quality assurance program may include routine review of the site's standard operating procedures (SOPs). This process helps refresh the team's knowledge of the SOPs and also helps them determine whether modifications are needed to current SOPs or new SOPs should be written. The internal quality assurance process may in itself help the team determine new SOPs that should be developed. For example, new SOPs may be developed to address weaknesses identified through the chart reviews. In addition to reviewing the site's SOPs, the team should use this time to read and review the SOPs of the local institutional review board. All research staff should possess at least a basic understanding of the institutional review board's procedures.

In addition to chart reviews and internal audits, a site should consider implementing a quality assurance program that incorporates periodic external audits. External audits provide a site with invaluable information about the research program's

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strengths and weakness, enabling the team to develop an even stronger program. An external auditor may be contracted by the research site. Alternatively, the site might consider partnering with a sister site to audit each other's programs. Such a partnership can greatly reduce the costs associated with an external audit and promotes the sharing of ideas between the sites.

How a site implements an internal quality assurance program depends on the needs of the site and the resources that are available. Sites with adequate resources may select one experienced staff person who is dedicated to maintaining the site's quality assurance program. This person is often responsible for training staff, conducting chart reviews, and overseeing regulatory compliance. Sites that do not have the resources to dedicate one person to this task can still implement a successful program. These sites can assign position-appropriate tasks to each member of the team and, if resources permit, periodically engage help from experts external to the program for staff training and auditing.

Ultimately, the full potential of a quality assurance program rests with the leadership and active participation of the program's principal investigator. Not only can the principal investigator serve as a resource for the research team, but the he or she may also be called on to champion implementation of corrective action plans and to solicit cooperation from all members of the research program, including physician investigators.

Multidisciplinary Involvement in the Clinical Trial Process

Engagement of physicians and nonphysicians across disciplines will increase the strength of a research program. This increased breadth of knowledge and involvement will enable the site to offer more diverse and complex trials, ultimately providing more options for patients who wish to participate in clinical research. Promoting the research culture across disciplines will also increase the success of the research program and may lead to increased discussions with patients about trials participation.

A site should actively engage a broad spectrum of disciplines. Involving physicians from disciplines such as surgery, radiation oncology, radiology, and primary care should be considered. Collaboration between these disciplines is imperative for the success of multimodality studies and for patient recruitment and follow-up on all trial types. A helpful way to encourage colleague participation is to open trials that are of importance and interest to them. If the research program currently offers trials focused mostly on medical oncology, it may be helpful to consider trials offered through American College of Surgeons Oncology Group or the Radiation Therapy Oncology Group. The research program can also promote engagement by identifying colleagues who will serve as a local principal investigator on a trial. Active participation and influence across disciplines will help physicians more fully appreciate and understand the research process, ultimately leading to increased quality of research conducted at the site.

Beyond physician colleagues, it is important to also engage professionals such as pharmacists, dieticians, psychologists, nurses, and physical and occupational therapists. These individuals can contribute to the success of the research program both directly and indirectly, and their importance should not be underestimated. Staff who wish to play an active role in clinical research can provide expertise that enables the program to offer trials that might not otherwise be possible, such as trials related to prevention, quality-of-life, and survivorship. Support staff who are not directly involved in the research program are also important for promoting the research culture at the site. For example, individuals who provide direct patient care should have a basic knowledge of research so they can accurately answer basic patient questions about research, refer patients for more information, and assist with patient follow-up. Perhaps less appreciated is the frequency with which research participants may rely on the observations of the support staff. This underscores the importance of engaging these individuals in the research culture.

There are many ways a site can engage the larger provider community in the clinical trial process, including efforts to engage colleagues. At a scientific level, it is important to offer trials that are of interest to various specialities and ensure that physicians across disciplines are aware of the trials currently being offered. To do this, research staff should actively participate in meetings within the practice and the larger local health care system, such as tumor boards or disease-specific meetings. Some sites find it valuable to designate a physician champion who attends tumor boards and suggests trials that may be an appropriate option for the patient being discussed. When trying to engage colleagues who are not regularly at meetings held by the site, such as primary care physicians, it may be helpful to initiate a letter-writing campaign to these colleagues or to have the lead investigator personally contact them. Physicians who refer patients to the practice are important partners and may be willing to mention the possibility of participation in research at the time of referral. Developing a newsletter that discusses trials currently being offered at the site is also a helpful way to keep the provider community informed. This is also a good venue for publicly acknowledging the contributions and achievements of colleagues, further encouraging their participation. An easily accessible computerized list of all available trials will also greatly facilitate communication and accrual.

In addition, it is important that research be incorporated into the overall agenda at the site. Therefore, the topic of clinical research should also be on the agenda at management-level meetings and discussions. Messaging about the site's participation in clinical research should also be articulated in any marketing or communication efforts about the site, as well as included in patient information materials available in the waiting room. Support from all staff at the site will help ensure that clinical research is ingrained into the fundamental mission of the organization.

Clinical Trial Awareness Programs

The nature of a research site's awareness program varies on the basis of the size and needs of the research site. The overarching goal of an awareness program is to increase knowledge about clinical trials in the greater community and among professional colleagues. Promoting awareness requires a broad approach that

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incorporates all disciplines at the research site and engages stakeholders in the community served by the site. Beyond increasing the community knowledge about clinical research, awareness programs promoting clinical trials enable the success of the research program and ultimately lead to the successful completion of clinical trials.

A first step in developing a clinical trial awareness program is to know the demographics of the patient population at the practice. Once the demographics have been assessed, awareness efforts can be targeted accordingly. For example, if the primary population is elderly patients, then educational information about clinical trials should likely be in print form. Younger populations might prefer to seek health information electronically, necessitating that the program consider electronic means of disseminating information. Often a program will develop both print and electronic educational materials to increase the reach of the site's efforts.

The awareness program should also focus on ethnic minority and underserved populations. It is important for the team to understand any barriers that limit these individuals from participating in clinical trials and develop methods for overcoming such barriers. Engaging key leaders and organizations within these communities who can help increase awareness about trials is important. Members from the research team should also participate in community events such as health fairs and cancer screenings. These mechanisms help build trust and rapport in the community and ultimately lead to more informed individuals who have acquired a basic understanding of clinical trials before being approached about participation.

Despite awareness efforts in the community, it is still likely that some patients will have little knowledge about clinical trials before being diagnosed with cancer. These patients can greatly benefit from patient navigator programs, which often involve a nurse or a trained patient advocate helping the patient find their way through the cancer care continuum. Whether or not the patient ultimately enrolls in a clinical trial, they will benefit from having access to an individual external to the research team who can answer their general question about clinical research. Patient navigators can also assist the research team through involvement on the protocol review committee. The patient navigator's understanding of the patient experience will help ensure that clinical trials offered at the site are practical and of interest to patients in the community being served.

Seemingly obvious but often overlooked, education and promotional resources about clinical trials should be readily available at the research site. It is important to show that clinical research is a routine and valuable component of cancer care at the practice level. For example, posters about clinical research should be posted in waiting and exam rooms to encourage patients to seek more information and talk with their provider about clinical research. Even if a patient is not currently eligible for a trial, this messaging introduces the topic in the event that participation is an option in the future. The patient may also wish to contribute in another way, such as participating in a research registry or donating biospecimens for research purposes.

Feedback Request

Suggest future topic ideas for the series and provide your feedback by sending an e-mail to researchresources@asco.org.

It is important that the clinical trial awareness program evolve in line with the specific and evolving needs of the research site and patient population. Therefore, the team should periodically evaluate the success of the program and determine whether modifications are needed. Some research sites may pursue the expertise of a marketing consultant to help develop the awareness program. However, an awareness program can be just as successful when developed and promoted by internal staff and patients of the practice.

Summary

This two-part article was developed on the basis of an education session at the 2010 ASCO Annual Meeting and aims to provide practical advice to investigators and their teams who want to implement one, or all, of the attributes of exemplary clinical trial sites. These voluntary attributes were developed by ASCO in 2008 to provide guidance to investigators who want to exceed the good clinical practice guidelines.

ASCO recognizes that research sites that want to implement the exemplary attributes may be limited by insufficient resources. Acknowledging this challenge, the ASCO Cancer Foundation has developed grant and award opportunities related to the exemplary attributes. More information about these opportunities is available online at http://www.ascocancerfoundation.org/. ASCO has also developed a Web page to provide sites with additional educational resources related to the practice of clinical research: www.asco.org/clinicaltrialresources. New to this page are free, online videos recorded by experts in the field of clinical research.

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