ASCO Outlines Minimum Standards and Exemplary Attributes for Research Sites: Previews Tools to Be Provided

As part of ASCO's continuing effort to best serve its members, Robin Zon, MD, FACP, Neal J. Meropol, MD, Robert B. Catalano, PharmD, and Richard L. Schilsky, MD, recently published an ASCO Special Article: *American Society of Clinical Oncology Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites* online on April 7, 2008 and in the *Journal of Clinical Oncology,* May 20, 2008. This statement is the most recent product of ASCO's commitment to support oncologists and other professionals engaged in clinical research.

Today, only a small percentage of cancer patients participate in clinical trials and receive care in places ranging from large regional or academic medical centers to community hospitals and private practices. Large academic medical centers focus on clinical research but eighty five percent of cancer patients are not treated at large centers, however, but in their own communities. One identified barrier to patients' participation in clinical trials is the lack of participating physicians. Recognizing the importance of educating and providing resources for all oncologists who are engaged in research or beginning their own clinical research programs, ASCO is committed to assisting them with incorporating clinical trials into their practices. Statement author Richard L. Schilsky, MD, relates, "My involvement in drafting this statement is well-timed as I begin my ASCO Presidential term. I feel very strongly that ASCO should play a key role in developing tools and resources to support and promote oncologists' involvement in the research process."

The statement broadly covers three areas. First, it defines a quality clinical trial research site as one that is compliant with the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. These guidelines were developed in part after World War II, as an attempt to establish a comprehensive code of ethical principles that would guide researchers in humane research regarding human subjects. They have been updated and agreed on during international meetings since then. In 1974, the US incorporated these principles into the Food and Drug Administration's regulations.

Second, the statement describes how good clinical practice guidelines are codified in different places, but that the overall effect of following them is to ensure "study results are credible and accurate" and "most importantly, that the rights, integrity, and confidentiality of trial participants are protected." In order to conform to the comprehensive and complex GCP guidelines, many clinical trial sites adopt standard operating procedures (SOPs) that they follow when conducting any trial. The statement includes a table that lists suggested topics for SOPs. Statement author Robert Catalano, PharmD, who serves as Vice President of Regulatory Affairs for the Coalition of Cancer Cooperative Groups, says "It is important for ASCO to set GCP standards as the baseline for quality research because following these standards will help sites ensure quality data and regulatory compliance."

Third, the statement names and describes seven attributes of exemplary clinical trial research sites. (See box below.) Statement author Neal Meropol, MD, says, "This is an important step in encouraging research sites to consider how to assess the quality of their programs and consider ways to enhance their research activities." ASCO proposes the attributes as performance goals, rather than requirements, and recognizes that they may not apply in whole across each research setting. As part of the statement reads: *This description of the features of an exemplary clinical trial site is intended as an initial guide for planning of a clinical trials enterprise and for designing an individualized self-evaluation process . . . It is hoped that further research will help clarify appropriate metrics of success that will ultimately facilitate the achievement of excellence by those wishing to conduct cancer clinical trials.*

A Subcommittee of ASCO's Cancer Research Committee (CRC) will provide practical information on how to implement the standards and attributes in a series of articles,

Exemplary Attributes of Clinical Trial Sites

In addition to the recommended minimum criteria, compliance with the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines, most of which are already formalized in the U.S. by Food and Drug Administration regulation, these attributes are suggested:

- Diversification of clinical trial mix
- High accrual activity
- Participation in the clinical trial process
- Formal maintenance of high educational standards
- Quality assurance
- Multidisciplinary involvement
- Clinical trial awareness programs

beginning with this one, to be published in the *Journal of Oncology Practice* over the next year and a half, fulfilling the Journal's promise of being the authoritative resource for practicing oncologists. This first article and its companion, written by Dr Zon describe the statement and how it came to be produced. The following topics in the series will, broadly, cover applying the exemplary attributes to everyday clinical oncology practice.

In each article of the series, a closer examination of one or more of the named attributes will be combined with descriptions of particular implementation steps that physicians at a research site can take. Experts from each skill area will provide the information necessary for researchers to begin considering how they might integrate one or more of the exemplary attributes into their own research program.

ASCO hopes that the series as a whole may encourage researchers to consider how to enhance their research programs and also to give clinicians not already involved in research a clearer understanding of what it involves.

ASCO is developing other resources and tools that will work in concert with the Statement and this series of articles. For example, a conference call has been tentatively scheduled for early September, during which the statement authors will describe their work, mention additional points to consider, and take questions from call participants. Information about the call is posted on the ASCO Web site at www.asco.org/researchresources. More information about additional tools and resources being developed to help practitioners adopt exemplary attributes of clinical trials into their sites will be included in forthcoming articles as well as the Web site.

Guidance for Quality Research
By Robin Zon, MD, FACP

Robin Zon, MD, FACP

ASCO is committed to providing oncologists with resources to assist them in incorporating clinical trials within their practice. The ASCO Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites is an example of ASCO's continuing efforts to promote the development of cancer research programs in an effort to promote quality care and advance cancer treatments. ASCO has historically supported community clinical research enterprises by recognizing high quality research sites with the Clinical Trials Participation Awards program and through providing education opportunities at the Annual Meeting and the Clinical Trials Workshop (www.asco.org/ctw). Publication of the ASCO Statement signals the beginning of a new series of initiatives to support quality oncology research.

The genesis of this statement is in response to the National Cancer Institute's Report of the Clinical Trials Working Group: Restructuring the National Cancer Clinical Trials Enterprise. The Working Group recommendations include a proposal for a credentialing system for clinical research sites. Rather than establish criteria for research program certification, ASCO decided it would be useful to develop a statement describing a quality clinical research site. By direction of the Board, the Cancer Research Committee formed a subcommittee, comprised of academic and community-based researchers. As I reflect on the development of the statement, I cannot underscore enough the importance of the collegiality of the subcommittee members.

As the subcommittee deliberated over the components of the statement, we thought it would be important for ASCO to affirm the Good Clinical Practice (GCP) Guidelines as the basic standard for conducting research. Following these guidelines helps ensure that a trial site has quality procedures in place and generates valid data. Once the GCP standard was defined, the subcommittee identified attributes that tend to exist in exemplary clinical trial sites. ASCO views these attributes as performance goals for those research programs wanting to exceed the minimum standards. The attributes are not intended to be an exhaustive list, but instead provide guidance.

These attributes may appropriately evolve as clinical trial methodology, requirements and processes change. In addition, the attributes may also apply in whole or in part across different types of research sites. Importantly, with this statement ASCO recognizes that any site that is in compliance with Good Clinical Practice is conducting quality research.

Certain facts are indisputable: oncologists participation in research is low (estimates are less than 20%), 85% of cancer patients are seen in the community setting, approximately 50% to 60% of clinical trial accrual is from the community, and only 2% to 7% of all cancer patients are participating in clinical trials. It is clear that the community oncologists' contribution has enormous potential for accelerating the clinical trial process resulting in improved care for our patients. This statement provides guidance that has potential for communities to raise the bar of local oncology care with a research program.

ASCO recognizes that in addition to the statement, the Society should develop resources to assist researchers in effectively integrating the clinical practice guidelines and relevant exemplary attributes into their practices. As individual clinical trial sites will not necessarily meet each attribute discussed, the site should select performance goals and benchmarks appropriate for their patient mix, patient volume, demographics, and funding. In follow-up to this article, I am chairing a subcommittee of the Cancer Research Committee that is developing a series of "soup to nuts" articles offering practical and instructive advice on how to implement Good Clinical Practice, develop proper infrastructure, assess site accrual barriers, develop an outreach program, and improve involvement in the research process. The subcommittee is also developing related activities that will include the development of enduring materials utilizing the Web site and offering opportunities to interact with experienced colleagues. In addition to these series of articles, ASCO is promoting application of the exemplary attributes through a new grants program—the Community Oncology Research Award. ASCO awarded these grants to three community practices at the 2008 Annual Meeting based on a written description of what the practice will do to move toward one or more of the exemplary attributes. ASCO's intention is that these awards will serve as a laboratory for testing ways to implement the attributes.

These are exciting times for cancer research. The last two decades of basic and translational research have ushered in an era wherein hundreds of potential therapies to prevent, treat, and cure cancer are on the doorstep, waiting to be validated as effective interventions. The turning point for changing the direction of cancer's fate is here, and the community oncologist has the opportunity, and perhaps even the obligation, to be a major force in completing the research voyage our colleagues started so seemingly long ago. Through the conduct of high quality research and by challenging ourselves with the suggested performance goals, it is possible to revolutionize cancer care and the quality of life for our patients, while meeting the goal of reducing the cancer burden worldwide.

"Commitment is what transforms a promise into reality."

Abraham Lincoln

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