



Site Performance Guidelines

Challenge

The Hoosier Oncology Group is facing trends in its recent actual performance and forecast estimates for accrual that could lead the number of accruals that originate in academic sites to be the majority of accruals rather than the historic and mission-based predominance through community practices.

As we address drift from a core component of the Hoosier Oncology Group identity, there is a real need to focus limited Hoosier Oncology Group resources on those sites fully committed to being members (sites) in deed as well as word. The Hoosier Oncology Group recognizes that low performance not only results in a drain of limited Hoosier Oncology Group resources, but also contributes to costly inefficiencies at the research site level.

Objective

The Hoosier Oncology Group would like to increase accruals by all its members, especially in the community setting, where the majority of oncology patients are treated. The Hoosier Oncology Group strategy establishes expectations and monitoring performance related to:

1. Site accrual
2. Research staff and physician participation
3. Quality, speed and value scorecard

The success of this strategy will be based on cooperative actions: support by Hoosier Oncology Group tools and resources coupled with member effort and investment.

Background

The Hoosier Oncology Group has featured prominently in the development of research infrastructure to conduct cancer research in community settings since its founding in 1984. Published data states that 85% of oncology patients are treated in the community setting, however less than 5% of cancer patients participate in clinical trials. The Hoosier Oncology Group is committed to bringing high-quality studies that are relevant and easily implemented in a community setting.

Benefits of HOOSIER ONCOLOGY GROUP Membership

Full and Limited members have many benefits of participating with the Hoosier Oncology Group.

1. Access to world-class academic physicians at Indiana University's Simon Cancer Center, the Hoosier Oncology Group Research Base.
2. Access to high-quality studies that advance the medical field's understanding of how to best meet the needs of cancer patients.
3. Pride in authorship for high accruing sites.
4. Participation in study development at inception based on medical interests and need observed within member practices at bi-annual Clinical Trial Working Group meetings.
5. Training for Site Coordinators at the bi-annual Site Coordinator meetings to learn and share best practices for conducting research thru relationship building.
6. Ability to participate in Advisory Groups with Research Nurses and Patient Advocates to optimize protocols for patients and sites.

Performance

Member performance is measured on several different levels with response outlined as appropriate.

Annual Performance Standards:

Standard 1: Hoosier Oncology Group Members are required to accrue a minimum of 5 patients annually to be considered in good standing. If this minimum is not met in the calendar year, the site will be placed on probation and have six months to improve accrual to that level or membership will be revoked. At the conclusion of the six months, the site will have an opportunity to petition the Board to extend the probationary period by an additional 6 months, provided the site has implemented a plan of action to improve accrual. The site may exercise an option to participate in a *Research Program Assessment/Consultant Engagement* program, sponsored by the Hoosier Oncology Group, to help achieve accrual goals. The cost of this program will be the site's responsibility and negotiated at the time of the request for service.

Standard 2: Hoosier Oncology Group Members must have at least one participant attend at least one CTWG and one Study Coordinator Meeting/Teleconference Annually. Participation may be accomplished by meeting in-person or by teleconference.

Annual Performance Goals:

Goal 1: Hoosier Oncology Group Members will be expected to accrue participants at 75% of the site's Feasibility Survey commitment in order for the Hoosier Oncology Group to make business decisions reflective of total membership participation. This goal will be monitored and may be considered by the Board in evaluating a site's probationary, renewal or request for full membership status.

Goal 2: Hoosier Oncology Group members that rise to the top 30% of the Annual Performance Scorecard will be recognized as **Research Role Models**, and be invited to participate in a Peer Site Audit or Protocol Advisory Group review. Weighted scorecards will be based on Quality (Query % Rank), Speed (Data entry completion cycle time Rank) and Value (% enrollment to accrual commitment Rank). Members in the top 60% of

performance scorecards will be allowed to nominate their staff as candidates for the *Sandra Turner Award* which awards a continuing education stipend for the winner.

Goal 3: Hoosier Oncology Group Members Sites which accrue 20+ patients will be identified as a **Premier Research Member**, and those accruing 10+ patients annually will be identified as a **Signature Research Member** in the Hoosier Oncology Group Annual Report and Press Release.

Goal 4: Hoosier Oncology Group investigators who accrue 10% or more of the originally stated or amended clinical trial accrual goal, will have opportunity to be an author on any publication related to the clinical trial. The top 5 accruing investigators of any clinical trial will be offered opportunity for presentation and/or 1st or 2nd authorship of publications, as determined by the specific clinical trial chair. Member sites will be expected to identify and validate, for the Hoosier Oncology Group staff, the site investigator(s) with the highest accruals for individual clinical trials.

Expectations

Exemplary Attributes of Clinical Trial Sites (*Journal of Clinical Oncology*, Vol 26, No 15 (May 20), 2008: pp. 2562-2567 © 2008 [American Society of Clinical Oncology.](#))

Meeting the minimum criteria is necessary to conduct quality clinical trials; however, some sites may wish to incorporate additional performance goals to exceed GCP compliance. Among the important attributes of an exemplary clinical trial site are the following: diversification of the clinical trial mix; high accrual activity; participation in the clinical trial development process; maintenance of high educational standards; quality assurance; multidisciplinary involvement in the clinical trial process; and promotion of clinical trial awareness programs. This list of attributes is not meant to be exhaustive; additionally, fulfillment of each criterion is not necessary for a particular site to achieve excellence in the clinical trials enterprise. Rather, our goal is to provide a palate of characteristics for consideration by those clinical trials sites wishing to exceed minimum and necessary requirements. Sites should review and implement these characteristics in the context of their particular demographics (eg, size, patient mix, practice setting), resources, and goals. Practice- or institution-based infrastructure devoted to integrating all aspects of the research enterprise can help facilitate achievement of exemplary attributes.

Diversification of Clinical Trial Mix

Established clinical trial sites may wish to diversify the types of clinical trials offered to provide the broadest array of options for patients treated and to maximally use their clinical research infrastructure and resources. A site's trial mix could include treatment, prevention, quality of life, symptom control, and biologic correlative trials.

Treatment trials offered may include phase I to III trials, as appropriate, and efforts should be made to develop a clinical trial portfolio that meets the diverse needs of the population served by the practice. Because patients who are willing to participate in a treatment trial often have a heightened awareness of the importance of clinical trials, they may be candidates for simultaneous enrollment onto symptom control, quality of life, and biologic correlative trials. In cases where individuals elect not to enroll onto a treatment trial, these

same individuals may still choose to enroll onto a symptom control or laboratory science trial. There is increasing recognition of the importance of correlative studies involving blood and other tissues. The NCI has developed a useful resource document for sites that outlines the best practices for biospecimen collection.²¹ Whereas the infrastructure requirements for phase I clinical trials and biospecimen collection may not be feasible in many community practices, this setting may be more conducive to other types of investigation (eg, phase III treatment or prevention studies).

A unique opportunity can be made available for family members of individuals diagnosed with a malignancy to also participate in the clinical trial process; for example, risk assessment and prevention trials can be offered. Scenarios such as these demonstrate how diversification can assist a research site in maximally using the existing resources and infrastructure while successfully improving accrual and addressing the needs of the community.

High Accrual Activity

One goal of an exemplary clinical research site should be to demonstrate the highest accrual activity possible for the area demographics within which the site practices. Ideally, an exemplary clinical trial site would accrue at least 10% of its patients on clinical trials. However, each site should establish its own benchmark based on a critical analysis of its patient volume, patient mix, and available clinical trials. Furthermore, ongoing assessment of progress and goals is encouraged. Recognizing that there are sites where demographics allow for potential accrual of under-represented populations, it would be appropriate for such sites to assess and improve current methods for engaging these populations. Timely activation of a trial can help maximize accrual, optimize access for patients, and reduce time to study completion and analysis. Working closely with the scientific review committee and IRB locally and using central IRBs when appropriate can facilitate efficient study initiation.

Participation in the Clinical Trial Process

Active collaboration between the community practice, an affiliated academic center, and the trial sponsor can be instrumental in the development and implementation of clinical trials. Such involvement offers a venue for investigators and research support staff to provide scientific input, communicate concerns, assess resources, and address the practical aspects of conducting the trial at the community and academic sites, thus contributing to the successful implementation of the clinical trial. Examples of these activities include attendance at research meetings of the trial sponsors, developing and authoring a protocol, assuming leadership roles such as serving as the local principal investigator or coinvestigator for a trial, and volunteering as an active member on trial sponsor boards and committees.

Formal Maintenance of High Educational Standards

ASCO recommends that all US investigators be specialty board certified. Recognizing that international investigators may not have board certification as an option, it is suggested that certification should be obtained when available. GCP requires that research support staff be adequately qualified by education and training for the research-related functions they have been authorized to perform by the investigator. Certification of clinical research associates and coordinators provides evidence of their qualifications to serve in this capacity and is preferred but currently not mandated by the GCP regulations. Continuing education for investigators and research staff should be performed by exemplary sites. Many physician

investigators may not have received formal training regarding the regulatory issues governing the conduct of clinical research. Although GCP standards recognize that investigators may, and should, delegate a number of their responsibilities to qualified support staff, the investigators remain ultimately responsible for the conduct of the study and must demonstrate adequate supervision of their staff. Organizations such as the Society of Clinical Research Associates and the Association of Clinical Research Professionals offer classes that prepare the clinical research staff and investigator to conduct the highest level of research from a regulatory standpoint. In addition to ensuring high educational standards, providing staff with protected time dedicated to research activities can help ensure exemplary performance.

Quality Assurance

Research sites that internally implement quality assurance programs ensure adherence to GCP guidelines and the consistent generation of high-quality data. Quality assurance programs include routine self-audits, modification of existing SOPs or implementation of new SOPs for issues identified during the internal quality assurance process, recording of minor and major violations, and implementation of programs of corrective action. Exemplary clinical trial sites should also undergo periodic external audits to document and enhance the quality of their research enterprise.

As clinical sites implement information technology such as electronic health records (EHR), there will be an opportunity to select systems that facilitate the high-quality conduct of clinical trials by assuring accurate and timely data collection and audit activities. An electronic repository of current consent forms and updated protocols will help ensure that investigators at multiple sites within a research entity are accessing the most accurate information. Searching EHRs for potentially eligible patients can be performed by entering specific search terms, and digitized radiology studies can be archived for confirmation of response at the time of audit. The NCI has initiated a process to standardize case report forms that can be electronically submitted to research sponsors.²² Ideally, required data elements such as laboratory values and dates and chemotherapy doses can be transferred from the EHR directly into the case report form fields.

Although not considered an educational standard, it is an essential responsibility of the principal investigator to interact with the IRB. Possessing a basic understanding of the responsibilities and procedures of the local IRB, as well as the IRB's SOPs, is recommended to improve a site's ability to interact and work with the IRB.

Multidisciplinary Involvement

Multidisciplinary involvement of both specialty physicians and nonphysicians is desirable within any research setting. Increasing the breadth of expertise at a research site may permit an increase in the scope and complexity of clinical trials that can be offered, ideally resulting in higher accrual at a particular site. The ability to increase practitioner participation depends on area resources. In addition to medical oncology, physician disciplines to be considered as investigators include radiation oncology, surgery and its subspecialties, pathology, radiology, and primary care physicians. Although multimodality studies clearly require the coordination of several subspecialties, single-modality trials also may benefit from efforts at coordination and involvement with other specialties (eg, adjuvant treatment studies) for patient recruitment or follow-up. Although primary care physicians do not prescribe cancer therapies, they may contribute as champions for cancer

prevention trials or survivorship studies. Other health professionals who may contribute to cancer research include clinical pharmacists, psychologists, clinical research coordinators, and nurses, all of whom could potentially contribute in the areas of cancer control research and patient recruitment, as well as cancer treatment.

Clinical Trial Awareness Programs

Clinical trial success depends on accrual; therefore a value-added element that a research site may consider is implementing a program to increase awareness in both the lay and physician communities. If potential participants and physicians do not know trials are available, then accrual will be slow. There are a number of ways to increase awareness; however, community, institutional, and individual practice resources may dictate the extent of marketing efforts to facilitate participation. Plans to increase awareness may include educational programs directed toward the public and physicians, with emphasis on including minorities and underserved populations. Participation in local health fairs and cancer screening events provides additional opportunities for educating the public. Many avenues and resources for raising awareness currently exist that a site could easily integrate into a planned program. Examples of Internet-based resources are listed in [Table 2](#). Ideally, the program would undergo periodic review and adapt to the changing needs of the site and the community. Sites may also wish to involve patient advocacy groups by either creating a community advocacy board or including a patient advocate on the protocol review committee.