

ASCO Expert Corner: What Makes a Quality Clinical Trial Site



A clinical trial is a research study involving people. To help oncologists (doctors who treat people with cancer) integrate clinical trials into their practice, the American Society of Clinical Oncology (ASCO) developed [recommendations \[1\]](#) for the attributes of an exemplary clinical trials site. These recommendations were followed by a [series of articles \[2\]](#) in ASCO's *Journal of Oncology Practice* that provide practical information for oncologists on developing and maintaining quality clinical trial sites. To learn what patients should know about exemplary clinical trial sites, Cancer.Net talked with Richard L. Schilsky, MD in 2008. This article was updated in 2012.

Q: What is meant by an "exemplary clinical trial site"?

A: A clinical trial site is a doctor's office, clinic, or hospital that offers patients the opportunity to participate in cancer [clinical trials \[3\]](#). In order to do so, a clinical trial site must have in place a number of policies and procedures that ensure research participants are protected from harm, that the study's protocol (set of rules) is followed, and that the data collected are accurate. The standards that must be met by all clinical trial sites are specified in a set of documents known as Good Clinical Practices (GCP). ASCO believes that GCP standards should be met by every site that conducts clinical trials. Some sites have the ability and interest to expand their clinical trials participation beyond meeting GCP requirements and, in doing so, might be considered "exemplary" clinical trial sites.

Q: What are some common characteristics of exemplary clinical trial sites?

A: Exemplary clinical trial sites offer a diverse selection of research studies that reflect the needs of their patient population, enroll a high percentage of eligible patients in clinical trials, provide ongoing educational and quality assurance programs for research staff, participate in the design and leadership of research studies both locally and nationally, and promote clinical trial awareness in their communities.

Q: Why is ASCO making recommendations on minimum standards and exemplary attributes of clinical trial sites?

A: More than 80% of people with cancer receive care in their local community. ASCO strongly believes that all people with cancer should have an opportunity to participate in clinical trials, as clinical trials provide a high standard of medical care and help to develop new information that will benefit future patients. Many community oncologists choose to offer clinical trials in their practice to expand treatment options for their patients and to offer cutting-edge therapies. However, some oncologists may not know how to establish a clinical trials program in their practice or how to assess the quality of their clinical trials program. ASCO has decided to make recommendations regarding the minimum standards and exemplary attributes of clinical trial sites to assist oncologists in providing clinical trials to their patients, to help ensure that the rights and welfare of clinical trial participants are protected, and to provide guidance on research procedures that will ensure that the research data generated are accurate and can be used to draw valid conclusions about study outcomes that will benefit future patients.

Q: How will these recommendations affect patients?

A: By helping oncologists to develop exemplary clinical trial programs at their practice sites, ASCO hopes to expand the variety of treatment options available to patients and to increase the confidence that patients have in the safety and quality of cancer clinical trials.

Q: Is there anything else patients should know?

A: All oncologists are committed to providing the best possible treatment for each patient. Many oncologists choose to offer clinical trials to patients because they hope to advance the standard of care, while at the same time providing outstanding medical care. Clinical trials are closely monitored and regulated and include many safeguards for patients. Physicians who offer clinical trials are making a commitment to comply with applicable federal and local regulations and to have the appropriate procedures in place to ensure the welfare of patients who choose to become research participants. ASCO is committed to providing information to oncologists that will allow them to be exemplary participants in the clinical trials system.

Patients who have questions about clinical trials can find more information at www.cancer.net/clinicaltrials [\[4\]](#) or by contacting the Institutional Review Board at the hospital or medical center where they receive their treatment.

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More Information

[Cancer.Net Video: What Are Clinical Trials?](#) [5]

[Finding a Clinical Trial](#) [6]

[Questions to Ask the Research Team](#) [7]

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Links:

[1] <http://jco.ascopubs.org/cgi/content/full/26/15/2562?>

[2] <http://jop.ascopubs.org/content/4/6/280.extract>

[3] <http://www.cancer.net/all-about-cancer/clinical-trials/about-clinical-trials>

[4] <http://www.cancer.net/node/24863>

[5] <http://www.cancer.net/node/27106>

[6] <http://www.cancer.net/node/24878>

[7] <http://www.cancer.net/node/24881>