



# *Clinical Trials in Cancer Part I* **Biomedical, Complementary, and Alternative Medicine: Finding Active Trials and Results of Closed Trials**

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Cancer clinical trials are research studies of humans designed to answer specific questions related to cancer. Meticulously conducted cancer clinical trials are the fastest method to establish safe and effective preventive, diagnostic, treatment, and supportive care interventions (National Cancer Institute [NCI], 2004). Complementary and alternative medicine (CAM) is a pervasive component in cancer care, and cancer CAM clinical trials are increasing in number and expanding in design. Oncology nurses are at the forefront of clinical supportive care for patients enrolled in clinical trials. They also are involved in designing clinical trials, accruing participants, monitoring, managing and analyzing data, and reporting results.

The author of this article performed a search for conventional biomedical and CAM clinical trials in the United States and offers a synopsis of how to locate active trials and published results. Part II of this article, to be published in a future issue, will review significant aspects of cancer CAM clinical trials, such as accrual, ethical and methodologic considerations, use of CAM in symptom management trials, and the role of nursing in cancer CAM.

## **Types of Clinical Trials**

Six predominant types of clinical trials exist: prevention, screening, diagnostic, treatment, supportive care, and genetic studies (NCI, 2004). Treatment trials studying new therapies or new indications of drugs, vaccines, and approaches to treatment compose the majority of clinical trials. Supportive care trials studying ways to improve cancer-related symptoms and quality of life are the sec-

ond most common type of trial. Ancillary studies such as those that examine quality of life or pharmacoeconomics and nursing companion studies (Aikin, 2000; Hohenstein, 2000; Tokarsky, 2000) can be categorized in one of the previously mentioned trial types. Although all trial types are conducted for conventional biomedical interventions, only three trial types currently are conducted for cancer CAM clinical trials: prevention, treatment, and supportive care. Table 1 offers explanations of all trial types with examples.

## **Phases of Clinical Trials**

Three main phases of clinical trials exist: phase I, II, and III. Phase I trials generally involve a small number of patients ( $N < 50$ ) and focus on how, when, and at which dose a new drug should be given. Phase II trials generally involve one type of cancer, focus on drug safety and efficacy, and comprise the majority of conventional biomedical and cancer CAM clinical trials. Phase III trials generally involve a larger number of patients ( $N > 100$ ), use randomization, and compare new approaches with standard ones. Phase I and III trials are fewer in number for conventional biomedical and cancer CAM clinical trials. After a treatment has been approved by the U.S. Food and Drug Administration (FDA) and is marketed, it is studied in a larger, phase IV trial ( $N > 1,000$ ) to evaluate side effects that were not apparent in the phase III trial. The author performed a single search in the NCI Physician Data Query® (PDQ) database for cancer clinical trials ( $N = 1,982$  trials) and CAM clinical trials ( $N = 102$  trials). See Figure 1 for a comparison of trials by phase.

## **Locating Clinical Trials**

Despite increased interest in CAM clinical trials in general, only 3%–5% of patients with cancer in the United States participate in any type of clinical trials (Varricchio, McCabe, Trimble, & Korn, 1996). Typical sponsors of trials are NCI-generated programs such as the Cancer Centers Program, Clinical Trials Cooperative Group Program, Cancer Trials Support Unit, Community Clinical Oncology Program, and the National Institutes of Health (NIH) Clinical Center. Pharmaceutical and biotechnology companies sponsor trials that take place in academic centers, hospitals, clinics, and doctors' offices. A metasearch for eligible databases revealed four optimal sources for retrieving clinical trial information related to cancer care in the United States: Center Watch™ Clinical Trials Listing Service, ClinicalTrials.gov, PDQ, and Trial Check™. These databases provide varying levels of access for healthcare providers, patients, and researchers (see Table 2).

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