

The Nurse as Principal Investigator in a Pharmaceutically Sponsored Drug Trial: Considerations and Challenges

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Purpose/Objectives: To discuss the process, considerations, benefits, and challenges of the nurse as principal investigator in a cancer care drug trial.

Data Sources: Published articles, anecdotal experience, and completed research studies.

Data Synthesis: The specific processes that must be considered are funding sources, protocol development, trial implementation, dissemination of results, and ethical implications involved in industry sponsorship. Specific protocols are designed for evaluating adverse events. Working with pharmaceutical companies to receive financial support offers advantages but poses additional issues for consideration.

Conclusions: Nurses can serve successfully as principal investigators in medication trials for cancer care. Regulatory bodies and specific procedures, as well as general considerations, mandate and guide investigator conduct when embarking on a pharmaceutical trial.

Implications for Nursing: Oncology nurse researchers can look to pharmaceutical companies for potential funding in the evaluation of medications used in cancer care.

Historically, nurses have assumed the role of coordinator or research nurse rather than principal investigator (PI) in cancer pharmaceutical trials. Nurses who are appropriately prepared and partnered with a physician are permitted to assume leadership of clinical research involving medications (U.S. Food and Drug Administration [FDA], 2002). Current trends in health care, nursing, and the pharmaceutical industry are merging to maximize opportunities for oncology nurses to assume leadership in pharmaceutical clinical trials.

One important trend in health care is the increased interest in evidence-based practice. All healthcare providers are challenged to provide care based on evidence of efficacy rather than tradition or habit (Hewitt-Taylor, 2002). The need for evidence-based practice has resounded throughout the cancer care continuum. According to the National Institutes of Health (2002) *State-of-the-Science Statement on Symptom Management in Cancer: Pain, Depression, and Fatigue*, further research involving symptom management strategies should include the development and evaluation of new treatments for pain, depression, and fatigue. The symptom management statement called for clinicians to “conduct studies to investigate the effectiveness of combinations and sequencing of pharmacologic and nonpharmacologic treatments” and to “incorporate pharmacogenomic and pharmacogenetic studies into future randomized trials” (National Institutes of Health, 2002, p. 18).

Key Points . . .

- ▶ Pharmaceutical trials from concept to result dissemination can be difficult and complex, with unique considerations related to industrial sponsors.
- ▶ Doctorally prepared nurses are uniquely positioned to assume the role of principal investigator in pharmaceutical trials.
- ▶ Real-life examples of specific challenges faced by principal investigators in drug trials can help to guide nurses as they design, implement, and conduct pharmaceutical trials in the cancer clinical setting.

Other trends include increased public demand for use of medications for symptom management, the increased attention to the need for postmarketing drug surveillance, and the number of advanced practice nurses in oncology with prescriptive authority. Direct-to-consumer pharmaceutical advertising results in more prescriptions for the most heavily advertised drugs (Murray, Lo, Pollack, Donelan, & Lee, 2004). Many of these direct-to-consumer claims have not been evaluated specifically in cancer populations. This allows a rich opportunity for pharmaceutical trials to use medications for symptom management specifically in a cancer population or within a subset of patients with cancer. Recent attention to drug safety and adverse events in widely used medications has alerted all clinicians to the need for continued drug monitoring and evaluation of medications used for symptom management in specific populations.

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