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Are Cancer Trials Valid and Useful for the General Surgeon and Surgical Oncologist?

Waddah B. Al-Refaie, MD*, Selwyn M. Vickers, MD

Department of Surgery, Surgical Outcomes Research Center, University of Minnesota and Minneapolis VAMC, MMC# 195, 420 Delaware Street Southeast, Minneapolis, MN 55455, USA

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• Applicability

Key Points
- Cancer trials represent a rigorous and clear approach to test whether an intervention or treatment will alter the outcomes of individuals with cancer in an experimental manner that is beyond the level of observational studies. As such, they remain useful and valid to the day to day practice of general surgeons and surgical oncologist.
- However, the short comings of current cancer clinical trials need to be recognized, especially when less than 1% of adults persons with cancer participate in cancer clinical trials, thus leaving the generalizability of these trials to patients and their surgeons in the real world setting an open question.
- Moving forward, physicians, payers, professional societies, advocates, the NCI, and other stakeholders need to develop broader cancer trials to benefit the millions of patients with cancer in the US.

CANCER CLINICAL TRIALS AND THEIR IMPORTANCE TO ALL STAKEHOLDERS

Well-designed and properly executed randomized clinical trials (RCTs) remain powerful investigational tools to assess the efficacy of cancer treatments in improving the survival and quality of life of persons with cancer. RCTs are critical to the everyday practice of cancer care among surgeons because they provide high-quality evidence to guide treatment recommendations for the patient who has cancer in real-world settings. However, achieving these goals

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*Corresponding author. *E-mail address*: alref003@umn.edu

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also requires wide-scale adoption and dissemination of trial results into day-to-day clinical practice [1,2]. As such, the traction and engagement of stakeholders remains crucial. These stakeholders include patients with cancer, clinicians, the National Cancer Institute (NCI), payers, regulators, professional societies, policy makers, and patient advocates [1,2].

In addition to their impact on patients with cancer, the extent to which these cancer trials benefit other stakeholders is important for several reasons. First, results from properly conducted, adequately sampled, and well-stratified cancer trials create an environment of highly streamlined, research-driven treatment guidelines, thus encouraging stakeholders to better adhere to research-based treatment recommendations to increase accrual of subjects to newly introduced clinical protocols. Second, when applicable to the practice of clinicians, trials also engage more surgeons to participate and enroll their patients as subjects in cancer trials. Third, high-caliber cancer trials incentivize professional societies, policy makers, and payers to support this strong level of evidence, thus discouraging them from supporting practices in which unnecessary (and perhaps underinvestigated) therapies are administered [1,2].

WHY ARE CLINICAL TRIALS UNIQUE TO PERSONS WITH CANCER?

Cancer trials provide a rigorous and clear approach to testing whether an intervention/treatment will alter (or not alter) the outcomes of individuals with cancer in an experimental manner beyond the level of observational studies. The impact of a treatment or intervention on a designated end point is compared with a control group with a premise to minimize bias and confounding [1,2]. As such, cancer trials are particularly important to persons who have, or are at risk of, cancer because of many key points. First, adequately powered and well-stratified cancer trials are designed to improve the survivorship of persons with cancer. Second, clinical trials also measure whether these oncologic interventions improve the quality of life of their enrollees in the setting of anticipated survival benefit [3–7]. Third, the results of cancer trials allow surgeons and other clinicians to better understand the natural history and biology of various cancer sites, especially when interventions (or lack of them) are interposed [8]. Fourth, cancer trials also provide their enrollees opportunities to access research-driven hospitals and cancer centers, to participate in treatment decisions, and to be closely followed up. Fifth, high-caliber clinical trials will guide and streamline oncologic treatment decisions, thus leading to effective, but resource-conserving, clinical practice, rather than maximally tolerated treatment.

Because of the changing profile of cancer in the United States, cancer trials are timely and particularly important to persons who have, or are at risk of developing, cancer and their surgeons. First, cancer is a leading cause of death in the United States, second to heart disease. Second, the overall demographics of persons with cancer in the United States are evolving. For example, more than 60% of solid organ malignant tumors are diagnosed in persons older than 65 years, with an estimated 85% of all cancer deaths attributed to this elderly population. Twenty