Nearly 8.5 million Americans who have had cancer are alive today. These individuals are living longer and experiencing a better quality of life than ever before, in part because of continuing advances in cancer care. Most of these advances stem from clinical research studies that rigorously test new ways of treating cancer or of reducing the side effects of existing treatments. For example, curative treatments for leukemias, lymphomas, and germ-cell tumors were developed as the result of clinical trials, and the longevity for people with breast and colorectal cancer has risen in recent years because of clinical trials that carefully evaluated the efficacy of new therapies [1,2]. Other clinical trials have helped establish better ways of caring for cancer patients, for example, using less-invasive surgical procedures and reducing negative side effects [3,4,5].

Traditionally, the cost of conducting cancer clinical trials has been supported by a combination of research sponsors, institutions, and third-party payers. However, health insurers and other payers are increasingly reluctant to reimburse for direct patient care provided as part of a clinical trial [6]. This reluctance—driven in part by a perception that patients enrolled in trials incur substantial additional costs—impedes efforts to enroll patients in clinical trials. Yet there is little evidence regarding the costs of treating patients in clinical trials.

Given the great importance of timely clinical research, there is thus an urgent need for unbiased information on the possible effects of participation in government-sponsored clinical trials on patient care.
costs. Such data would make any cost-sharing burden explicit and could lead to better mechanisms for financing clinical trials.

In this report, we summarize current knowledge on the additional costs, if any, of treating cancer patients in clinical trials. We outline some methodological challenges facing any effort to generate precise and generalizable estimates of these costs. Finally, we introduce the Cost of Cancer Treatment Study (CCTS), an ongoing effort to obtain national estimates of the direct care costs of patients who participate in National Cancer Institute (NCI)-sponsored clinical cancer trials (see www.costofcancer.org).

One caveat should be noted at the outset. Clinical trials involve administrative and research costs beyond direct care, including staff training, trial administration, analysis, and reporting. All of these costs—which are underwritten by research sponsors such as NCI, institutions, or industry rather than insurers—are beyond the scope of this study. They clearly warrant further investigation.