We thank Schoen for her comments and insights into accrual performance. The primary purpose of our research was to reveal the relationship between development time of National Cancer Institute Cancer Therapy Evaluation Program (NCI-CTEP)-supported trials and a standard accrual milestone that was established at time of study activation (1). We completely agree that it is important to confirm our findings and that using a less restrictive definition of accrual sufficiency might lead to new insights into the impact of development time on eventual accrual success rates.

One factor that requires additional research is the definition of a "successful" outcome of a trial. Multiple other studies have implied that achievement of sufficient accruals is an important outcome metric. For example, Schoen and colleagues (2) reported that 35% of 248 phase III therapeutic trials opened by 5 national cooperative groups between 1993 and 2002 did not achieve sufficient accruals. At a single institution, she observes that more than half of phase III trials closed to insufficient accrual (3). Similarly, Go and colleagues (4) reported that "over a quarter of the trials" of all Eastern Cooperative Oncology Group (ECOG) phase II and phase III trials from 1977 to 2006 failed to achieve accruals goals and complete. And Korn and colleagues (5), using the most liberal definition of success, reported that 26.7% of 1919 CTEP-sponsored phase III trials from 2000 to 2007 failed because of accrual issues. Our study may present a higher incidence rate of phase III trials that do not achieve sufficient accrual, as our limited sample set includes only trials with complete records for both development time and accrual performance, although our overall study cohort of 419 trials resulted in 37.9% poor accruing CTEP-sponsored trials, which is in line with other approximations. Regardless of the exact percentage, clearly there is an underlying issue with both development time and accrual for oncology clinical trials that demands further research. We have diagnosed the problem, and we must now collaborate our efforts to construct innovative approaches to remedy this indisposition.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

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