A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program

A recent Institute of Medicine (IOM) report (1) cited several deficiencies in the Clinical Trials Cooperative Group Program of the National Cancer Institute (NCI), including an inefficient and cumbersome oversight structure and a 20% reduction in funding since 2002. The authors concluded that these and other problems have resulted in start-up times for phase III Cooperative Group trials that range from 1.25 to almost 7 years and a clinical trial completion rate of only 50%. They also noted that clinical trials of cancer treatments are increasingly located outside the United States.

Although the oversight structure and funding decline at the NCI may be partially responsible for the observed problems, demographic and market forces are also likely causes. We searched ClinicalTrials.gov for trials registered since 2005 that involved adult cancer patients and found that planned enrollment in NCI-sponsored clinical trials—the number of patients the investigators intended to enroll at the start of the trial—declined from 2.90% of new US cancer cases in 2005 to 1.79% in 2009 (Table 1). During this same time period, planned enrollment for all other (ie, non–NCI-sponsored) US-based adult clinical trials of cancer treatments increased from 3.24% to 4.62% of new US cancer cases.

These trends illustrate the diminishing role of the NCI in the sponsorship of US-based clinical trials in both absolute and relative terms. As planned enrollment in NCI-sponsored trials has decreased, planned enrollment in commercially sponsored trials has increased. Whether a more efficient and better funded NCI would have been able to prevent this trend is debatable. Planned enrollment for all US-based cancer clinical trials averaged more than 6% of all new US cancer cases over this time period, which is more than double the 3% figure the IOM authors cite as the historical average. Considering the slow increase in the number of new US cancer cases per year and the rapid increase in commercially sponsored clinical trials, the observed reduction in enrollment in NCI-sponsored trials might have been unavoidable. Lengthy trial completion times, low trial completion rates, and a shift away from US-based trials would also be likely consequences.

For clinical trials of treatments for certain types of cancer, the potentially available participants may be especially scarce. For example, planned enrollment for leukemia trials equaled 12.8% of new US cases from 2005 to 2009. The rate for breast cancer trials equaled 8.9%.

As the IOM report authors noted, "publicly funded clinical trials play a vital role by addressing questions that are important to patients but are less likely to be top priorities of industry." This statement underscores the importance of achieving an optimal mix of publicly and privately funded clinical trials. With the limited number of potential participants in clinical trial in the United States, policy makers will need to consider methods to increase patient participation in cancer clinical trials or, alternatively, ways to allocate enrollment between publicly and privately funded clinical trials with a goal of improving clinical trial completion rates.

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Table 1. Planned US trial enrollment divided by the number of new US cancer patients

Trial start year	No. of new US cancer patients*	Planned US trial enrollment†/ No. of new cancer patients (%)		
		NCI-sponsored trials	Other-sponsored trials	Total
2005	1 349 922	2.90	3.24	6.14
2006	1 375 718	2.81	3.84	6.65
2007	1 406 840	2.02	4.14	6.16
2008	1 437 373	1.81	3.73	5.54
2009	1 464 339	1.79	4.62	6.41
2005–2009	7 034 192	2.25‡	3.92‡	6.18‡

* Based on US Census population data and cancer incidence estimates from the Surveillance, Epidemiology, and End Results Program.

† From ClinicalTrials.gov.

‡ Percentages for the combined years 2005–2009 given as weighted averages of the annual percentages in the cells above.

Reference

1. Committee on Cancer Clinical Trials and the NCI Cooperative Group Program Board on Health Care Services; Nass SJ, Moses HL, Mendelsohn J, eds. *A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program*. Washington, DC: National Academics Press.

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