Has Demand for Clinical Trial Participants Outpaced Supply?

Clinical trials are a critical resource for the discovery of new preventive, diagnostic, and treatment methods for cancer. However, current estimates show that less than 10% of adult cancer patients in the United States participate in clinical trials (1). Low trial participation combined with the requirements of larger patient populations per trial and more trials in each study phase for drug approval (2) may prolong drug development and ultimately increase drug costs. We evaluated whether the demand for trial participants may be outpacing the current “supply.”

We searched the proposed mandated repository for clinical trials information (http://www.clinicaltrials.gov) from October 24, 2005, to November 14, 2005, for all actively recruiting US trials that involved breast, lung, or prostate cancers. We excluded trials that involved more than one type of cancer. The total number of trials and the total number of patients required for study completion were recorded for each type of cancer. For trials that recruited participants from both the United States and other countries, we counted 50% of the accrual. We also noted the study phase, the cancer stage, the type of therapy, and study sponsorship.

We identified 259 breast cancer trials, 188 lung cancer trials, and 168 prostate cancer trials based on the predefined criteria (Table 1). The number of participants needed for study completion is 123,975 for breast cancer trials, 26,660 for lung cancer trials, and 52,792 for prostate cancer trials. These numbers represent 58.7%, 15.4%, and 22.7% of the American Cancer Society estimates of the number of new cases of breast, lung, and prostate cancer, respectively, in the US population in 2005.

Phase II studies represented a major portion (51%) of the studies evaluated. Phase I and phase III studies represented 11.5% and 15.6%, respectively, of the studies, and the remaining studies were combined phase I/II or phase II/III studies. Academia, either solely or in collaboration, was listed most often (51.7%) as the study sponsor (i.e., the organization responsible for trial initiation and management), followed by the National Cancer Institute (44.4%) and industry (27.2%).

Our findings suggest that for some types of cancers, the demand for clinical trial participants may be outpacing the current supply. New treatments developed through clinical trials have likely played a role in the decline of cancer deaths for the first time in 70 years. To continue this trend, it is vital to improve the rate of patient accrual and to better address practical concerns, such as the inclusion of older patients, improvement in research site support, and physician and patient preconceptions about research trials.

It has been suggested (3) that the designs of current phase II trials (most of which are single-arm trials) are inefficient and that the results from these trials may not be sufficient to determine whether larger, more definitive phase III trials should be conducted. With more than 50% of the studies we reviewed being phase II studies, these trials also present a source of competition for subject enrollment. As the current

<table>
<thead>
<tr>
<th>Cancer type</th>
<th>No. of trials in database</th>
<th>ACS cancer incidence estimate for 2005</th>
<th>Total No. of patients needed for study completion (% of ACS 2005 incidence estimates)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td>259</td>
<td>211,201</td>
<td>123,975 (58.7)</td>
</tr>
<tr>
<td>Lung</td>
<td>188</td>
<td>173,117</td>
<td>26,660 (15.4)</td>
</tr>
<tr>
<td>Prostate</td>
<td>168</td>
<td>232,564</td>
<td>52,792 (22.7)</td>
</tr>
</tbody>
</table>
estimates of clinical trials participation is less than 10%, the designs of phase II trials may represent an area for further evaluation.

Addressing potential barriers to patient enrollment in clinical trials (4,5) will continue to be important, especially as the population ages. Despite the fact that older cancer patients comprise a large percentage of adults with cancer, their enrollment onto clinical trials is limited (6,7). The under-representation of older cancer patients in clinical trials often limits the clinical applicability of study findings for this population.

The development of novel mechanisms to increase awareness and understanding of clinical trials in both the medical and public communities and addressing organization infrastructure issues to improve efficiency of study conduct are important issues to address. Formation of a national panel that includes the medical community, the government (i.e., the National Cancer Institute and the Food and Drug Administration), the public, and the pharmaceutical industry may facilitate this process.

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