Re-engineering the Cooperative Groups

In April, the National Academy of Science published its report, “A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program” (available at: www.nap.edu). The document is required reading for those interested in clinical trials in oncology, but the findings will not surprise those who have participated in cooperative groups trials. The groups deserve great credit for important clinical advances, conducting phase III trials that often define standards of care.

At the same time, the processes that govern current development and administration of studies are too complicated and too slow, as well as highly inefficient and woefully underfunded. Some sobering statistics:

- Only 60% of NCI-funded cooperative group trials reach their accrual goal;
- The accrual of 25,000 patients per year requires the involvement of 3100 treating institutions, suggesting an average accrual of 8 patients per site per year;
- The vast majority of patients at all cancer clinics are not treated on studies; Funding for the cooperative groups in general has been stagnant for the past decade;
- Per capita funding for cooperative group trials both lags industry-supported trials and is considered sufficient to cover only one third to one half of the costs of participating in a clinical study;
- The slow development and accrual to studies limits the scientific value of many trials.

The report calls for both intellectual and administrative changes to the cooperative groups process. It identifies goals of enhancing the speed and efficiency of trial development; identifying innovative science and trial designs; improving the prioritization, support, and completion of studies; and creating incentives for patients and physicians to participate. It encourages groups to focus less on trials of principle interest to industry and more on areas in which industry support is often lacking. These include trials on comparative effectiveness, use of novel agents from different sponsors, rare diseases for which collaboration is essential to finding adequate numbers of patients, and explorations of dose, schedule, and duration, as well as trials that integrate multi-disciplinary care from surgeons, radiation therapies, and medical oncologists and trials of prevention, quality of life, and rehabilitation.

A key piece of the proposals for reform is streamlining groups into more centrally organized units with less direct competition. In essence, the plan envisions an “Intergroup” process for each disease, led by disease-specific units with proven track records of success. It also recognizes some of the financial and professional challenges this would entail. In particular, it acknowledges the need for innovative ways to reward academic investigators for supporting studies, even if they are not part of the shrinking core of leaders who will be involved in vetting the trials and authoring the results.

The existence of a national infrastructure for conducting cancer clinical trials is unique to the United States, and the NCI cooperative groups have played a major role in transforming cancer care over the past 30 years. The report from the National Academy of Sciences is a worthy document that should cause all investigators to think about ways of supporting the group programs, making them more efficient and powerful for generating knowledge that will help cancer patients.

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