Revamping the Clinical Trials System

As cooperative groups begin to merge, priorities and funding patterns are being redrawn

When the National Cancer Institute (NCI) started its clinical trials cooperative groups in 1955, few people believed that smoking caused lung cancer and radical surgeries to extirpate cancer were the norm. Since then, findings from studies undertaken by the cooperative groups have shaped oncology practice and prolonged the lives of cancer patients by identifying and evaluating new treatments. But the operation of the cancer clinical trials system hasn’t kept pace with the science.

Last year the Institute of Medicine (IOM) reported that the cooperative group program “is falling short of its potential” and is “approaching a state of crisis.” The analysis noted that designing and initiating a trial can take years due to lengthy and redundant steps in the approval process. Some trials never open because the questions they seek to answer are no longer relevant by the time they receive approval. It also declared that the system lacks a suitable process of prioritizing and selecting trials as well as adequate funding.

NCI and the cooperative groups themselves have started to address many of the report’s recommendations, including the consolidation of 10 existing cooperative groups into 5—4 dedicated to cancer in adults and 1 to cancer in children. Merging the groups, many researchers say, will lead to greater efficiencies in the development and conduct of clinical trials.

The first new group emerged in July: the Alliance for Clinical Trials in Oncology. That’s the new name for the American College of Surgeons Oncology Group (ACOSOG), Cancer and Leukemia Group B (CALGB), and North Central Cancer Treatment Group (NCCTG), which have joined forces. “Each of our individual groups has scientific and organizational strengths,” says former ACOSOG co-chair Heidi Nelson, a professor of surgery at Mayo Clinic. “We are optimistic that when we join together, the sum will be greater than the individual parts, and the new scientific opportunities will advance patient care.”

The American College of Radiology’s Imaging Network (ACRIN) and the Eastern Cooperative Oncology Group (ECOG) will merge their research programs. So will the National Surgical Adjuvant Breast and Bowel Project (NSABP) and the Radiation Therapy Oncology Group (RTOG). Members of the Gynecologic Oncology Group (GOG) may partner with one of the newly formed groups. SWOG, formerly the Southwest Oncology Group, plans to maintain its current structure. The Children’s Oncology Group (COG), the only pediatric group, is not affected by this consolidation.

As they consolidate, the groups will standardize their protocols, auditing rules, and consent forms. They will register clinical trial participants using common information systems. Additionally, the groups will share resources such as tissue specimens. Clinical trials already under way will continue to follow their existing processes so as not to disrupt critical research.

FINDING FUNDING

Changes also are coming to the federal funding mechanism through which the cooperative groups will apply for multiyear NCI grants. Although it hasn’t yet been written, a Funding Opportunity Announcement, which should be released in July 2012, will outline the criteria by which studies will be reviewed, ranked, and funded. Notably, all of the cooperative groups will submit their funding requests on the same cycle, allowing for greater comparison of projects across the groups, says NCI’s Jeffrey Abrams, associate director of the Cancer Therapy Evaluation Program.

Unsurprisingly, competition for funding will remain stiff. The total amount of NCI funding available for all of the groups is currently $150 million. Although the IOM report points to this low level of funding as a barrier to the groups’ progress, that investment could remain stagnant. The rising cost of clinical research is a confounding factor.

“We are going to have to do fewer trials because the cost of doing the trials has gone up,” says James Doroshow, deputy director for clinical and translational research at NCI. With the coming-of-age of personalized medicine, he explains, patients must undergo several tests to categorize their cancer and ensure that they are appropriate candidates for a trial.

Escalating costs often prevent institutions from enrolling patients in clinical trials, says George Demetri, senior vice president for experimental therapeutics at Dana-Farber Cancer Institute, an outspoken advocate of revamping the clinical trials system. Currently, cooperative group trials allot $2,000 for the care of each patient enrolled in a trial. But the costs associated with taking the time to explain the trial to the patient, run preliminary tests, document test results, and provide care and follow up treatment usually far exceed that amount. That leaves individual institutions to make up the difference, with “a real chilling effect on research,” says Demetri.

“We are looking at an entirely new model for reimbursement,” says Doroshow. Part of the plan is to reimburse cancer centers that enroll large numbers of patients at a higher rate. “We’ve had lots of discussions with the cooperative group chairs about what that rate should be, but it hasn’t been established yet,” he notes. ■
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