Redesigning NCI’s Clinical Trials System: Integration Is the Goal

Should there be a national tumor tissue bank? Should there be core facilities that trial investigators can access for biostatistics resources, image analysis, and other kinds of support? Should government, universities, and drug companies develop a single contract template to cover most clinical trial issues? These questions and two dozen others are under active discussion in the National Cancer Institute’s clinical trials working group (CTWG), the committee charged with redesigning the NCI’s clinical trial system. The questions are posted on a new Web site, which invited comments from experts and interested parties in six areas under scrutiny by the working group.

Established earlier this year, the CTWG’s purpose is to eliminate “duplication of effort and fragmentation in the clinical trial system, which wastes resources and slows the clinical trial enterprise,” according to a statement by NCI director Andrew von Eschenbach, M.D., published last August. The issues are not new—many were tackled in the Armitage Report 7 years ago—but this redesign effort is the first to focus on all of NCI’s trials, including those conducted through the cooperative groups, the community clinical oncology programs (CCOPs), the specialized programs of research excellence (SPOREs), cancer centers, phase I and II contractors, individual investigators (R01s), and program project grants (P01s).

Under the present system, these disparate groups often do not talk to each other, said Karen Antman, M.D., NCI’s deputy director for translational and clinical research, who co-chairs the CTWG’s subcommittee on “harmonization” of trials across these groups. Antman emphasized that one benefit of a more integrated system is efficiency. “I think we owe it to the taxpayers,” she said.

But she also argued that integration of trials would be more effective. One thing that convinced her of that, she said, was that each of NCI’s progress review groups, the expert panels that review research needs for specific kinds of cancer, has called for a consortium of researchers from different settings to focus on that kind of cancer. “But we can’t do each [cancer] separately,” she said. “We need a system solution.”

One focus of Antman’s subcommittee is data sharing, including a “a web-based clinical trials registry confined to high-quality studies listing all federally funded studies.” Current databases of trial results, such as those maintained for cancer centers and cooperative groups, are separate and there is no database for trials carried out through grant mechanisms, Antman said.

In the subcommittee on standardization, candidates for more uniform procedures include case report forms, the conduct of correlative studies, endpoint validation to assess drug efficacy, and the credentialing of investigative sites and personnel.

Collaborations are suggested in several questions. For instance, the committee will consider whether both the NCI and the U.S. Food and Drug Administration should participate in certain meetings with drug companies that now involve only one agency or the other, such as the FDA’s end-of-phase-II meetings and the NCI’s Drug Development Group meetings. The working
group will also consider whether joint fellowship positions would facilitate productive collaborations among the NCI, academia, industry, and the FDA.

Problems related to collaboration are also under consideration. The accrual subcommittee asked respondents to identify barriers to use of the NCI’s Cancer Trial Support Unit, a central, web-based service that lists about 60 trials from different cooperative groups and makes it possible for any credentialed investigator to enter patients on these trials. Although the CTSU has made much progress since it was established in the wake of the Armitage Report, many trialists are still not using this collaborative mechanism, said Richard Schilsky, M.D., of the University of Chicago, who co-chairs this subcommittee. “We need a better understanding of why not,” he said.

Schilsky said that the accrual subcommittee has discussed the barriers to participation in trials—such as costs, paperwork, regulatory burdens, greater demands on patients, and the difficulty of finding trials—and is now looking for ways to overcome these. “We are focusing on specific activities to help [create incentives for] the process at all levels—the physicians, the patients, and the system,” he said.

The subcommittee on prioritization of trials solicited respondents’ own ideas on how best to improve prioritization of trials. The possibility of setting priorities centrally sparked controversy earlier this year when committee members’ concerns about agenda-setting at the national level were leaked to The Cancer Letter.

As the CTWG continues its discussions, James Doroshow, M.D., who chairs the CTWG, said that an implementation plan and possibly a new oversight body would be in place by June when the working group reports on its recommendations.

“As the CTWG continues its discussions,” Doroshow wrote in an e-mail, “one of the topics at the forefront is how to best establish an external body to oversee the entire NCI clinical trials process. Right now, it’s not clear how that should be done, but, by June, the CTWG will have a plan for implementing its recommendations and for oversight of the complex spectrum of NCI clinical trials.”

For more information, visit http://nciebforums.nci.nih.gov/ictQuestions/login_form.

—Caroline McNeil