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NCI Committee Attempts To Redesign *Cooperative Groups* Without Doing Harm

If one is to follow the tradition of employing the metaphor of war to describe cancer research, then the clinical trials cooperative groups would be likened to heavy tank divisions slogging steadily forward to *push back the enemy lines.*

Deploying more than 8,500 investigators and 1,400 institutions that place a total of 20,000 patients on cancer clinical trials every year, the 12 NCI-funded cooperative groups have set treatment standards and helped reduce mortality and morbidity of some of the most common cancers in the U.S.

The acceptance of the groups' results is unquestionable. Group

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In Brief:

Levine Leaves NIH For Pittsburgh; Fischbach Leaves Harvard For NIH; NCI Researcher Dies

ARTHUR LEVINE, scientific director of the National Institute of Child Health & Human Development, was appointed senior vice chancellor for health sciences at Univ. of Pittsburgh and dean of the School of Medicine. Levine is former chief of the Pediatric Oncology Branch in the NCI Division of Cancer Treatment. He joined NCI in 1967 as a clinical associate following his residency in pediatrics at Univ.of Minnesota Hospitals. He became branch chief in 1975 and moved to NICHD in 1982. . . . **GERALD FISCHBACH**, chairman of neurobiology at Harvard Medical School and Massachusetts General Hospital, was named director of the National Institute of Neurological Disorders & Stroke. . . . **HAROLD "RED" STEWART**, who joined NCI in 1937, the year it was established in Boston, died May 30 at the home of a daughter in Bethesda.He was 98. He moved to Washington with NCI in 1939. He retired as chief of pathology in 1969 but continued as an NIH research scientist emeritus until retiring completely in 1996. Stewart served as president of the American Association for Cancer Research, helped found the American Society of Clinical Pathologists, the International Academy of Pathology, and the Registry of Experimental Cancers. . . . **THE CANCER LETTER** won an honorable mention from the Society of Professional Journalists, 1998 Washington Dateline Awards, for coverage from January to April 1997 of the debate over mammographic screening for breast cancer for women in their forties. The award recognized a series of 11 articles, published in six issues of the newsletter, over the four months.

Goals Are To Speed Trials, Provide Greater Access

(Continued from page 1)

studies routinely take the premier slots at the annual meetings of the American Society of Clinical Oncology. Cumulatively over the past five years, the groups presented 16 of the 26 papers at ASCO's plenary sessions. Last April, one cooperative group, the National Surgical Adjuvant Breast & Bowel Project, made headlines—and altered medical practice—when it released the results of the Breast Cancer Prevention Trial.

Steady progress notwithstanding, NCI is redesigning the groups. Institute officials say their objective is to rebuild the clinical trials system around technologies that would simplify—and boost—accrual and make trials faster and less cumbersome. According to proponents of redesign, the groups need to expand and retool to test the emerging therapies and to demonstrate to skeptical health insurers and government agencies that evidence-based medicine is cost-effective.

Under the new doctrine championed by NCI, every oncologist should have the ability to put any patient on a clinical trial, NCI Director Richard Klausner said in an address to the ASCO annual meeting last year (**The Cancer Letter**, May 30, 1997).

For at least a decade, the cooperative groups have been hampered by stagnant accrual of patients as well as slow activation and conclusion of trials. Group chairmen lay the blame on bureaucratic procedures involving NCI, FDA, and Institutional Review Boards, redundant regulatory and administrative tasks, the increasingly burdensome responsibility to follow all patients until death, and, most important, lack of adequate government funding to do the job.

Meanwhile, the pharmaceutical industry has developed a parallel system that self-finances clinical trials in order to speed drugs to the market. At times, the companies pay physicians five times as much as cooperative groups to put patients on trials. Unlike most groups, the companies provide the physicians with data managers to handle the paperwork. While group investigators develop protocols on their own time, the companies typically pay their employees to develop protocols and handle administrative and regulatory issues.

"I don't want to say there is a crisis, but if we don't do something soon, we are headed down a difficult path," said Allen Lichter, ASCO president and member of the NCI Clinical Trials Report Implementation Committee, a panel formed by the Institute to retool the group system.

"If you take an organization like the cooperative groups, underfund it as dramatically as it has been underfunded, and keep it going long enough, the system will collapse," Lichter said to **The Cancer Letter**. "It is much simpler to fix the system than to build a new one."

Determining how to fix the system without destroying it has been a recurring theme in the committee's discussions over the past six months. Efforts to redesign the groups are not limited to NCI. Four cancer organizations— the Cancer Leadership Council, the Cancer Research Foundation of America, the Coalition of National Cancer Cooperative Groups, and the Oncology Nursing Society—have scheduled a "Summit on Clinical Trials," for July 15-16, in Washington, under the auspices of The March: Coming Together to Conquer Cancer.

Long-Term Funding

NCI funding for the cooperative groups has remained stagnant at about $87 million to $90 million annually for the past several years, during a time when research costs have risen about 3 to 5 percent per year. Though many groups receive "outstanding"

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and "excellent" ratings in peer review, none receive more than 50 to 60 percent of the funding amount approved by the Cancer Clinical Investigations Review Committee, the panel that reviews the groups.

Besides the lack of adequate federal support, the groups are threatened by the continuing expansion of managed care. Many HMOs and insurance plans refuse to cover the costs of patient care provided on clinical trials.

Physicians and institutions in effect donate their time to the national cancer clinical trials program, said Robert Comis, chairman of the Eastern Cooperative Oncology Group. "In the past, people were able to donate 50 percent because there were margins. Now those margins are gone," Comis said to **The Cancer Letter**. "The government has to start paying a reasonable amount of money for the work that's being done."

NCI officials acknowledge that the group system needs greater funding. "We anticipate the need to increase funds for the cooperative group system," Michaele Christian, director of the NCI Cancer Therapy Evaluation Program, said earlier this week at a meeting of the committee studying the group system. "It is something we are working on. Everyone realizes the need to infuse more money into the cooperative groups."

Christian said a specific funding plan cannot be developed until the implementation committee completes its work. "We won't have specifics until we know what we are doing," she said at a June 8 meeting of the committee.

NCI's current funding proposal, the Bypass Budget for FY99, requests a "core budget" of $101 million for the cooperative groups, about $11 million more than the current year's funding for the groups. The core amount would "sustain at full measure the proven research programs" of the Institute, the bypass document states. The Bypass Budget, presented to Congress and the President each year, represents the Institute's professional judgement of the amount needed to address scientific opportunities.

The extra $11 million, spread over 12 cooperative groups, still would not cover the funding gap of about $70 million identified by peer reviewers.

In a separate section of the Bypass Budget, which offers ways to "create and sustain mechanisms that will enable us to rapidly translate our findings from the laboratory into practical applications," NCI requests a $60 million increase for the cooperative groups "to cover research costs for an additional 20,000 patients," doubling patient accrual to group trials.

In effect, the groups would be expected to double accrual for the same amount of money that peer reviewers say is needed in the system now.

Land Mines On The Road To Salvation

The NCI committee was formed last fall to implement the broad recommendations of a report written by the Clinical Trials Program Review Group, chaired by James Armitage, head of the Department of Internal Medicine at University of Nebraska Medical Center (**The Cancer Letter**, Oct. 3, 1997).

The Armitage report called for the formation of a clinical research study section, increased funding for the cooperative groups, additional salary support for group committee chairmen, reduction of data collection requirements, uniform data collection across the groups and cancer centers, and changes within the Cancer Therapy Evaluation Program to reduce NCI's role in reviewing protocols.

While the review group was unable to reach consensus on a specific strategy for restructuring the cooperative group system, the report tentatively suggested that if NCI funded fewer groups with higher funding levels per group, patient accrual could increase while costs could be lowered.

"We don't need to invent a new system, but we need to modify this one to let these clever folks do their job as efficiently as they possibly can," Armitage said at the time. "We need to remove obstacles from their path."

The implementation committee began meeting last December to develop a plan to remove the obstacles mentioned by Armitage, a job that has been as perilous as a stroll through a minefield. At times when discussions became excessively heated, committee members suggested that NCI hire a professional "meeting facilitator."

"It's a very big committee, and everyone gets to be heard, so it takes a lot of time," said committee chairman John Glick, director of the University of Pennsylvania Cancer Center. "Also, it is a very complex issue. It's a lot like an NIH consensus conference on mammography. People have different opinions."

The 37-member committee includes representatives from academic medical centers, cancer centers, cancer and AIDS patient advocates,

cooperative groups, the Community Clinical Oncology Program, FDA, NCI, and the pharmaceutical industry.

"It has been slow going," said committee member Deborah Collyar, president of Patient Advocates in Research, of Danville, CA. "These are politically charged issues."

"It took several meetings before the various groups within the committee found a common working thread," said committee member Robert Mayer, of Dana-Farber Cancer Institute.

The first meetings were driven by a CTEP proposal, initially presented at a meeting of cooperative group chairmen last November, for expanding physician participation in cooperative group trials, committee members said. The "Accrual Demonstration Project," as it was called, was intended to test the theory that more physicians would participate in clinical trials if patient entry were streamlined.

At present, the cooperative groups have different entry methods, enrollment forms, and requirements. NCI selected a contractor, the EMMES Corp. of Rockville, MD, to serve as a single "Clinical Trials Management Unit" that physicians would contact for entry information about phase III cooperative group trials.

The project would be tested in phase III trials of one or two cancers. Enrollment forms for the trials would be standardized among the cooperative groups. Two "cohorts" of physicians would be recruited as test subjects. Cohort A would be physicians in practice management organizations with no previous experience with putting patients on trials. Cohort B would be clinicians, perhaps from Community Clinical Oncology Programs, who were successful at enrolling patients on trials and who could troubleshoot the system.

CTEP would provide $1,500 per patient enrolled to physicians in Cohort A, and would expect to enroll 1,500 patients from those physicians over three years. Cohort B physicians would receive an additional $350 per patient over their CCOP funding, and enroll 300 patients over three years. The three-year project would cost $4 million.

Endpoints of the project were data quality, accrual, and comparison of cohort performance, NCI officials said to the group chairmen.

Fear Of Centralized Research

As the proposed CTEP demonstration project became a major focus of the implementation committee's meetings, cooperative group chairmen grew alarmed. "It appeared to the groups that NCI was attempting to nationalize the system," said a committee member who spoke on condition of anonymity.

Comis, representing all of the group chairmen, listed several concerns about the demonstration project in an April 10 letter to Klausner.

"It disengages our superb, academically based biostatistical and operational support programs from the conduct of our studies," Comis wrote. "It separates our cancer center and academically based investigators from the community based investigators, whose participation and loyalty we have worked so hard to cultivate, and it relegates them to the position of an uninvolved 'accrual engine.' The ADP would provide a financial disincentive to participate in our studies and would not begin to approach the incentive pharmaceutical companies provide to participants in their trials," wrote Comis, who is not a member of the implementation committee.

"Finally, the ADP would commit to a new venture significant funds that could be effectively used to explore alternatives within the system already in place," Comis wrote.

"The cooperative groups are able to adjust, change, and explore new options. But such changes will be successful only if we are involved in the process that leads to them....

"We are concerned that the direction of the discussion at present will lead to the consolidation of the cooperative group apparatus into a homogeneous national system, the direction of which will be determined at, and by, the NCI," Comis wrote.

"It is inconceivable that R01-based research would ever be centralized this way, divesting it of a richness of competitive, innovative thought and action."

"No Intention of Dismembering Groups"

Responding to the letter from Comis, CTEP Director Christian wrote:

"Many of your concerns appear to be based largely on an incomplete understanding of the work of the committee to date.

"The IC [implementation committee] has no intention of dismembering the cooperative groups, nor, for that matter, of recommending a reduction in the number of groups. In fact, one of the IC's

explicitly enunciated principles is to preserve the groups.... Indeed, the fact is that deliberations of the implementation committee have led to substantial change in the theoretical models that have been presented to them for consideration," Christian wrote in a letter dated April 15.

The ADP was now called the "Expanded Participation Project," Christian wrote. "None of the proposed models has ever suggested that the biostatistical centers or operations offices be separated from the conduct of studies, though some administrative functions which are duplicated in all *12* groups might well be consolidated," Christian wrote.

"Whatever the IC recommends will need careful pilot projects of its components prior to successful *implementation.... There will clearly need to be a* period of parallel systems during this evolutionary process."

Then, Christian raised an issue that continues to be debated in the committee: Control of the scientific review of cooperative group concepts for clinical trials. Currently, the groups develop protocols and take them for review to CTEP. One view, held by NCI officials, is that CTEP review is not rigorous enough. Another view, expressed by some cooperative group chairmen, is that CTEP review is redundant to the peer review that takes place as protocol concepts work their way up through each group's disease committees. The Armitage report recommended that CTEP reduce its review of phase II and III trials not involving new agents, and said the groups should have full authority over prioritizing clinical trials.

"The IC does not wish to create a scientifically homogeneous national system, but wishes to promote competition of the best ideas and prospective peer review of scientific concepts....which is less than optimal in the current peer review system of the cooperative groups," Christian wrote in the letter to Comis. "Many of the proposals discussed would be designed specifically to augment such competition of the best ideas, and to bring the extramural scientific community into the protocol (concept) review process that currently relies on the NCI staff."

Besides, the money won't be forthcoming until NCI is satisfied that the protocol review is toughened, Christian wrote.

"In the long run, full funding of the group program depends on its being evident that group science is as rigorously competitive and meritorious as that funded by other peer reviewed grant mechanisms," Christian wrote.

Implementation Committee's Vision

Glick maintains that, despite a rough start, the committee has agreed on a "vision" and general principles that should guide changes to the group system.

"We have a vision of an NCI cancer clinical trials system, which is to increase the speed of trial implementation, increase the speed of trial completion, increase accrual, broaden access to patients and physicians, and increase efficiency," Glick said to **The Cancer Letter**. "We want a fair, functional, and fast system that maintains the strengths of the current system, and cooperative groups should be fairly funded for the work performed."

Glick said general principles agreed on by the committee include: preservation of the cooperative groups; opening protocol access so that patients can enter protocols across all cooperative groups, regardless of their physician's affiliation; opening the system to ideas from outside the groups; simplification of some trials; uniform forms across all groups; simplified forms; faster Institutional Review Board approval through the use of regional or national IRBs.

"Nothing has been decided," Glick said. "The vision was the easiest thing. The question now is how to implement the vision."

Glick said NCI officials have not attempted to dictate the committee's deliberations. "There is no NCI hidden agenda," he said. "NCI is not trying to dismantle the groups, nor is this committee."

The committee voted unanimously that the groups should be preserved, and recommended increased funding for the groups, Glick said. "NCI simply wants a wonderful, national cooperative group system," he said.

Counter-Proposal From Cooperative Groups

At the time Comis sent his letter to Klausner, the cooperative group chairmen began a separate series of meetings to develop a counter-proposal to the CTEP plan.

"We, who work daily on these issues, should have a clear and sustained role in addressing the problems and their solutions," Comis said in presenting the proposal to the implementation committee at its meeting May 22.

The proposal would consolidate overlapping group functions into four areas: a "regulatory block," an "information block," a "science block," and a "technology block."

The regulatory block would consolidate all regulatory and drug distribution functions that are now performed by each group separately into a single "Cancer Clinical Trials Support Unit." The unit would be responsible for credentialing, auditing, regulatory issues with FDA, IRB certifications, and other administrative functions.

The information block would contain a proposed Clinical Trials Access Service, a web-based system to provide information on all cooperative group trials, through which patients could be directed to a nearby physician participant for any trial. The service also could provide on-line patient registration on trials by any physician credentialed by the groups.

Cooperative group statisticians are developing the proposed technology block, which would consist of standardization and simplification of forms for patient evaluation, patient encounters, and off-study documentation, as well as a uniform system for follow-up reporting. The groups chairs expect standardization of forms for breast, lung, colon, prostate, and gynecologic studies by November, Comis said.

In addition, the statisticians and data management leaders for the groups would develop a web-based registration process to allow investigators to register patients onto any trial, across all the groups.

The science block would consist of protocol development and design. This area of the group chairmen's proposal has not been fully conceptualized, Comis said. However, the group chairmen agree that the system should assure the development of high-quality studies, trials should be more open to community physicians, eligibility criteria should be more inclusive, and strategies to address the needs of patients with marginal performance status need to be developed.

In addition, a structure should be developed that would encourage the pharmaceutical industry to use the groups as the preferred phase III testing ground for new compounds, Comis said.

As cancer patients are living longer, the customary practice of keeping track of patients and their outcomes from the time they go off study until their death has had a major impact on group finances, Comis said. The groups now manage more than 100,000 patients in follow-up, he said.

The Cancer Clinical Investigation Review Committee estimated that groups spend the equivalent amount of resources to follow four patients post-study for every one patient undergoing therapy, Comis said. "Although we believe that the data included in our follow-up databases are critical to addressing major issues relating to long-term side effects, the development of secondary cancers, and other survivorship issues, it will be impossible to continue the existing follow-up procedures under the current funding constraints," he said.

Some groups have begun to shorten follow-up times, and procedures need to be standardized across the groups, Comis said. Centralizing the group systems for follow-up and shortening the years would reduce the burden on the groups, he said.

After Comis presented the group chairmen's proposal, some of the committee's previous frustration abated, some committee members said.

"The major step forward was an agreement to create some form of centralized entity that would take on regulatory affairs and facilitate cross-group registration," said committee member Richard Schilsky, chairman of Cancer and Leukemia Group B. "This was one of the first meetings where we felt we were moving toward closure on the process of improving the national clinical trials program.

"There had been a great deal of frustration," Schilsky said. "Some of it stemmed from the diverse backgrounds of the committee, and from the fact that the committee was only given an opportunity to consider one model of how to reorganize the clinical trials program, which was the model developed by NCI staff."

Collyar agreed that the May 22 meeting was encouraging. "The agreement to have a consolidated management area moves the system forward no matter what other elements are put in place," she said. "Everyone has finally accepted the fact that there need to be some major changes to the system."

CTEP Refines Its Model

In response to the implementation committee's discussions and the cooperative group chairmen's proposal, CTEP revised its proposal that would draw upon the Expanded Participation Project's concept of a Clinical Trials Management Unit to centralize trial administration, relieving cooperative groups of the redundant work that each group does in support of phase III trials.

Under the most current proposal, presented to the committee June 8 by Richard Ungerleider, chief of the CTEP Clinical Investigations Branch, and Richard Kaplan, of CTEP, NCI would pilot test two new entities:

—A Cancer Trials Support Unit (same idea as the CTMU, but using the group chairmen's name) would consolidate all administrative, regulatory, data management, and auditing for new phase III trials in two diseases, lung and gastrointestinal/urinary cancers. The CTSU could be contracted to a university, private firm, or a cooperative group. Enrollment and data forms for the selected trials would be standardized for all groups, and all groups could enroll patients on the trials.

—Disease-specific review committees to review phase III protocols. Protocol concepts could be submitted by cooperative groups, cancer centers, CCOPs, or individual investigators. Two committees would replace the current CTEP review process for phase III protocols in lung and GU cancers. CTEP's role would be limited to reviewing the protocols for completeness.

The two review committees would have about 15 members each, with one-third of the membership from cooperative groups, one-third from NCI staff, and one-third from other organizations involved in research including cancer centers, patient advocacy groups, CCOPs, and the NCI-funded Specialized Programs of Research Excellence. Ad hoc experts could be added to the committee as needed.

The committees would meet about every three months to rank each proposed protocol on some type of rating scale similar to the NIH R01 review. Only those protocols judged "outstanding" or "excellent" would be approved for activation across all the cooperative groups.

Data would remain the intellectual property of the group that proposed the trial. Physicians would be reimbursed by NCI, through the CTSU, for enrolling patients on trials. The amount would be $1,000 to $1,500 per patient.

A protocol concept not highly ranked could still be activated by the group that proposed it, but only that group's investigators could enroll patients on the trial.

Any trial proposed by an investigator outside the group system would have to work with an NCI-funded statistical center to help develop the protocol.

After a protocol concept is reviewed and approved, a faster process for writing and assembling all parts of the protocol could be developed, Kaplan said to the committee. Web collaboration would enable the group investigators, NCI, and statisticians to work on parts of the protocol simultaneously, he said.

"Once in place, the target time to protocol finalization should be less than 60 days," Kaplan said.

The groups are not convinced that the disease-specific review committees will work, some group chairmen said. "We are a little concerned about the feasibility," Schilsky said to **The Cancer Letter**. "If you expand it to 10 diseases, you will have 10 committees of 15 people each, meeting three or four times a year. We would like to see it piloted, and if it doesn't slow down concept development even further, then it could be expanded."

"I'm not sure that the CTEP approach with the review bodies is going to help expedite development of studies," Comis said to **The Cancer Letter**. "As you add that extra layer, you might lose more time."

CCOPs Favor Cross-Group Patient Entry

Having heard the CTEP presentation of its latest model, several CCOP principal investigators urged the implementation committee to ensure than any new system provides CCOP investigators the ability to enroll patients on any group study, regardless of the investigator's group affiliation.

"The way to enhance accrual is to give us more trials to put patients on," said committee member James Wade III, of Cancer Care Specialists of Central Illinois.

Currently, CCOPs are limited to participation in five cooperative groups. NCI is considering a pilot project to allow CCOPs to participate in more groups, said Leslie Ford, director of the Early Detection and Community Oncology Program.

The CCOP PIs also said that to ensure greater participation by community physicians, these physicians should be more involved in developing protocols. Also, the use of standard entry forms across the groups would help improve patient accrual, they said.

In addition, protocols tend to select only patients with good performance status, said Leslie Laufman, of the Columbus CCOP. "We need to write protocols for patients in the real world, those with poor renal function, for example," she said.

Greater funding for CCOPs also would help increase accrual, several PIs said. The physicians

who are most successful at patient enrollment have data managers in their offices to facilitate the process. "You need to support the CCOP mechanism," said Philip Stella, of the Ann Arbor Regional CCOP. "You can't expect busy doctors to put patients on trials unless you give them a data manager."

David King, of the Greater Phoenix CCOP, said the CTEP proposal appeared "extremely attractive," but left him wondering about the future role of individual cooperative groups.

"We have been complaining about these things for years," King said. "This is so attractive that it would be easy for me to look to this centralized group for all my phase III trials."

Individual cooperative groups would become "only a conduit for a few phase II trials," King said. "What, in the future, will be the role of the cooperative group?"

There would continue to be advantages for a CCOP to be affiliated with a cooperative group, Ungerleider said. "You may not be able to get all the phase III trials through your IRB," he said. "The natural impulse will be to stay with one group, and you'll go to their meetings. I don't see that the bond between the group and the CCOP will be eliminated."

Industry Trials, Early Trials

The implementation committee does not have a model for improving the ability of cooperative groups to work with the pharmaceutical industry, but committee members say this is one of the most important, and difficult, areas that require retooling.

"We would like to figure out how to convert a threat into an alliance," Schilsky said to **The Cancer Letter**. "The things important to industry are speed and control of the data. We need to work on how we can meet their needs."

Companies pay about $4,000 per patient and up to physicians who enroll patients in company-funded studies, while the groups can pay only $1,000 to $1,500, Schilsky said. "We need to create a system that would allow industry to use the groups to accomplish studies and infuse resources into the groups," he said.

"Industry provides cash on the barrel and it pays for your data manager," Mayer said. "They want to move things quickly to FDA for approval, while the major goal of the groups is to answer a scientific question. The fact that FDA will approve a new drug on a phase II result rather than a phase III result makes it easier for industry."

Even if the implementation committee can retool the groups, there remains a large area of early clinical research that needs greater federal support, said Robert Young, president of Fox Chase Cancer Center and a member of the NCI Board of Scientific Advisors. The groups tend to emphasize later, confirmatory studies, while traditional NIH grants emphasize basic research and translational research.

"We don't have in place a robust system for supporting novel pilot trials through a variety of funding mechanisms," Young said to **The Cancer Letter**. "The classical R01 and P01 grants won't do it, at least in their present form."

The group system tends to discourage trials that address controversial issues, Young said. Another way to support these trials would be for NCI to select an idea and assemble a group of investigators interested in participating. These groups could be formed and disbanded quickly, he said.

"My concern is that we are arriving at an endpoint where we are considering the groups as the only federally-funded mechanism to support clinical trials," Young said.

A Work In Progress

Implementation committee members said they expect the new models for changes to the group system to evolve over the next few months, and they acknowledge that the committee may not be able to address all the problems the groups face.

"This is a work in progress," Mayer said. "Funding [of the cooperative groups] and the relationship with industry, in my opinion, are the two major challenges that need to be resolved. Whether that is in the purview of our committee is somewhat unclear."

"I believe we should take as long as it takes to come up with a good system," Schilsky said. "I was pretty negative about this process a month or two ago, but the committee has come a long way. NCI has taken the discussions seriously. The group chairs have worked very hard at coming up with a model. Hopefully, the most useful aspects of the two models will be implemented."

"I think this is going to turn out well," Lichter said. "We started down a path that will make the clinical trials system in this country much better."

The committee is scheduled to meet July 31, and may hold a final meeting in late August. The committee plans to present a report to the NCI Board of Scientific Advisors in September, Christian said.