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Restructuring the NCI Clinical Trials System

by Jeffrey Abrams, M.D., and Mary McCabe, R.N.

A fundamental shift is underway in how the National Cancer Institute conducts clinical trials. The new system is more flexible and open to suggestions from every group that has an investment in clinical trials—patients, families, research assistants, nurses, community physicians, and research clinicians. Support from the entire oncology community is vital—first to evaluate the new system as it comes online, and second to participate in it. Major improvements should materialize within the next year or two. The entire clinical trials system stands to benefit.

Each year, physicians from across the country enroll thousands of patients in National Cancer Institute-sponsored clinical trials. Although these studies may ultimately improve cancer care, only 2 to 3 percent of cancer patients participate.

Large trials take a long time. They are paper-based, complex, and often cumbersome with multiple barriers for both patients and physicians. While many checks and balances are necessary to ensure patient consent and safety, clinical oncologists have asked for a quicker, easier way.

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NCI has responded to their request. In 1997 an NCI-initiated review, led by James Armitage, M.D., of the University of Nebraska Medical Center, recommended that the clinical trials process be streamlined, include ideas from a broad group of basic and clinical researchers, and encourage more physicians and patients to participate in trials. To shape these recommendations into a workable plan, NCI formed the Clinical Trials Implementation Group (CTIG), headed by John Glick, M.D., of the University of Pennsylvania and Michaele Christian, M.D., of NCI. The CTIG report outlined a comprehensive plan to restructure the way NCI conceives, reviews, and implements clinical research.

Two years after the Armitage report, testing of the new system is well underway. Several pilot projects have been launched to streamline the clinical trials system, to bring it online, and to make it more in touch with the needs of the oncology community. At the same time, the new system aims to reduce the crushing load of standard-issue clinical trials paperwork, expedite reimbursements, and significantly reduce the amount of time researchers spend achieving Institutional Review Board compliance. Promising therapies will be moved from bench to bedside more rapidly, while quality control checks that typify NCI-sponsored trials are maintained.

CHANGES IN THE PROTOCOL PROCESS

Under the restructuring, a new program will bridge the gap between laboratory and clinic for phase I and phase II trials. Called Rapid Access to Intervention Development (RAID), the program provides NCI funds (roughly $10 million each year) and expertise to researchers who have discovered promising new agents, but do not have the capacity to perform the myriad technical, logistical, and administrative tasks needed to ready their discoveries for human testing. Lab researchers who win RAID grants will receive help with initial toxicology screening, drug production scale-up, dose optimization, assay development, and any other tasks necessary to show "proof of concept" of the agents' anti-cancer potential. In some cases, the researchers may apply for help with a few specific tasks; in others, NCI may supply an entire portfolio of functions required to file a new drug application with the FDA for phase I clinical trials.

For phase III trials, several changes in the protocol development process are being tested in lung cancer and genitourinary cancers. One such change is the new "state-of-the-science" meetings, which replace the Cooperative Group-only strategy meetings traditionally held by NCI. The first state-of-the-science meeting focused on molecular targets for therapy in small-cell lung cancer. It convened September 1999 and brought together researchers and patient advocates. By mixing ideas from both basic and clinical scientists, the meeting fostered translational research and generated new approaches to targeted drug development and clinical testing. The second meeting, Molecular Targets for Prostate Cancer, was held in November 1999. Conclusions from each meeting are posted on the Cancer Research Trials Information Exchange web site, funded by NCI, at www.webtie.org/sots/sots.htm.

After a drug or treatment concept proceeds from benchside development to early clinical trials, the new review process will move it into phase III trials more efficiently. Under the current system, phase III trial proposals are limited to Cooperative Group members and reviewed by an NCI-only board. Under the new system, a broader range of researchers will be encouraged to submit proposals, which will be reviewed monthly by broad-based expert panels, called Concept Evaluation Panels (CEPs). One-third of each CEP's membership will be from NCI, two-thirds from the private sector, including experts in academia and industry.

During the pilot phase, the CEPs will be limited to lung and genitourinary cancers, with expansion into other cancers as the process is refined. Because the panels comprise experts from around the country, they will meet via a web-based teleconference, reviewing and voting on proposals posted on a password-protected site. (The first meeting of the Prostate CEP was in October 1999 and the Lung CEP was held in November 1999.) When a CEP approves a trial concept, it will move rapidly—within 60 days—to a final protocol. The trial will then be entered onto a menu of studies to be managed by a new NCI-funded group called the Clinical Trials Support Unit (CTSU).

MORE PHYSICIANS, MORE PATIENTS

The aim of the restructuring is to get trials up and running more quickly as well as to accelerate their conclusion, so new treatments can move more swiftly into standard practice. Phase III trials currently take on average four years to accrue patients, plus two to three more years of follow-up before results are published.

To increase patient accrual rates, NCI plans to build a broad national network of participating physicians who will have access to the CTSU menu of high-priority clinical trials. At first, network participation will be limited to Cooperative Group members. But within two years, any specialist—whether working in a large academic hospital or in a community setting—will be able to enroll patients via the CTSU's web site. Network physicians will not have to be Cooperative Group members but will have to undergo CTSU credentialing before they can enroll patients. The goal is to cut a year or more from the patient-accrual stage of each study.

Patients looking for clinical trials will find background information, other educational materials, and trial protocol summaries on a single NCI web site. When they search for a particular trial, they will be able to locate participating physicians and find out if their insurance will cover the trial.

ONLINE ENROLLMENT AND DATABASE

A multi-function database will serve as the foundation of the new NCI clinical trials system, minimizing paperwork while simplifying trial protocol administration, data entry, storage, and reporting.

In October 1999, the contract for this system—the CTSU—was granted to Westat of Rockville, Md., with subcontracts to Oracle Corporation for database support and to the Coalition of Cooperative Groups for its expertise in the daily clinical trial management. The five-year, $60 million budget includes funds for the information infrastructure as well as for reimbursement for researchers who enroll patients.

The system will be pilot tested starting summer 2000, with trials in five areas (genitourinary, lung, breast, and gastro-intestinal cancers, and adult leukemia). When a physician logs on, he or she will find trial summaries and eligibility criteria, along with full protocol descriptions. Online patient enrollment, data entry, and trial administration tasks eventually will be funneled through a dedicated web site, easing IRB oversight, auditing, and data reporting. This new online system should ultimately expedite reporting of results and accelerate improvements in patient care.

Browse NCI's Web Site

For more information and updates on the new clinical trials system go to cancertrials.nci.nih.gov., the NCI's web site for clinical trials. Here you can read an overview of the new clinical trials system by NCI investigators, who also present detailed explanations of its various components. Some of these components are already in place. Others, such as the state-of-the-science meetings and the CTSU, are just starting.

You can use the web site to register for updates on progress. NCI is gradually moving toward its goal of making its trials easily accessible to community oncologists, including those who want to participate in research, and their patients. You can also send NCI your comments on the web site and the information it contains.