

NCI extends clinical trials to community oncologists

By Brian Vastag

In spring 2002, the National Cancer Institute (NCI) took a significant step toward its goal of enrolling more patients in clinical trials: clearing the way for qualified oncologists who are not affiliated with a cooperative group to enroll their patients in large, NCI-sponsored phase III trials.

Now gathering momentum after several years of planning and start-up, the new program “is the perfect venue for community oncologists who want to participate in research,” said Jeanne Adler, RN, Ms. Adler helps run the program from the NCI’s Cancer Trials Support Unit (CTSUS). Officially it’s known as CICRS, which stands for CTSU Independent Clinical Research Site. “The beauty of the CTSU and CICRS is that rural oncologists and those in small cities and towns can now get their patients onto NCI protocols,” said Ms. Adler. “They’re able to receive cutting-edge cancer treatment right in their own community. Patients are always stressed, and it’s a real benefit to receive treatment close to home from

people they’re comfortable with.”

Phase III trials are the most reliable way to advance cancer care, but some 95% of adult cancer patients never join a trial. For years, NCI and the cancer community, acutely aware of the lifesaving potential of some 400 therapies stuck in the development pipeline, have been striving to increase clinical trial enrollment. An influential 1997 report, written by a committee chaired by noted University of Nebraska oncologist James Armitage, MD, recommended that NCI include more community oncologists in its vast network of clinical trials.

The institute set about reducing the barriers faced by oncologists in smaller practices. It recognized immediately that the primary barrier is that, traditionally, physicians had to belong to an NCI cooperative group to enroll patients in trials. Established in 1955, the cooperative group system has done most of the heavy lifting in the NCI trials universe. Twelve groups, organized by disease type or geographical region, receive \$150 mil-

lion while enrolling 25,000 patients in several hundred trials each year. In short, they form the cornerstone of the nation’s clinical cancer research. But Jeff Abrams, MD, a senior investigator at NCI and a chief architect of the CTSU, said that, although cooperative groups have contributed “enormously” to cancer research, they are geared toward experienced investigators at large cancer centers.

The CTSU began as a pilot project in 2000. But before opening up to community oncologists, NCI staff wanted to build administrative and data-tracking systems consolidating the cooperative groups. Traditionally, each cooperative group operated in a microcosm—every trial was “owned and operated” by a specific group. But through the CTSU, cooperative-group physicians are free to enroll patients in a number of important phase III trials. “By allowing cross-group registration, NCI was able to develop a universal clinical trials system while ensuring that participating researchers were qualified,” said Dr. Abrams. As of late August 2004, some 3,500 patients, or 14% of all the patients in NCI clinical trials, were enrolled via the CTSU.

With this early success, the CTSU opened in May 2002 to all oncologists not affiliated with cooperative groups. By late August 2004, 80 oncologists from 25 sites were credentialed and enrolling patients in trials.

How to join the CTSU

■ ONCOLOGISTS MUST FIRST SUBMIT an interest form available online at <http://www.ctsus.org>. They can also call the CTSU help desk at 1-888-823-5923.

■ CTSU staff members respond with specific information regarding the types of trials available and how to proceed. As of August 2004, the CTSU offered 53 clinical trials covering all the major cancers.

■ Interested oncologists submit a full

application, including a curriculum vitae, details regarding any previous clinical trials experience, support staff credentials, pharmacy access, and so on.

■ Applicants must have access to an Institutional Review Board. “To find an IRB, an applicant can get in contact with a nearby hospital that does research, or, if that isn’t practical, there are several commercial IRBs,” said Jeanne Adler, RN, a nurse who helps run the NCI program. “Very few interested oncologists have had trouble connecting with an IRB.” To

streamline the patient protection process, NCI is developing a central IRB that could eventually serve all CTSU investigators. “We’re very interested in exploring how the central IRB can assist sites without IRB coverage,” Ms. Adler said.

■ A CTSU panel reviews the application and contacts the applicant. Oncologists with limited clinical trials experience may receive a site visit, but most applicants instead are vetted via a conference call. “If the CTSU staff wants to confirm some information,

they will make a site visit,” said Ms. Adler. “But if an investigator presents very well and is experienced with pharmaceutical company or other types of clinical trials, then a phone interview will suffice.”

- The panel approves, conditionally approves, or disapproves the investigator’s application.

- If approved, the newly credentialed investigator receives an account for accessing the NCI’s clinical trials administrative system.

- To enroll a patient in a trial, investigators first download the trial protocol from the CTSU website and submit all required information to the appropriate IRB. After IRB approval, patients are enrolled.

- Investigators receive \$2,000 for each enrolled patient. All trial data are submitted via the CTSU Web site.

- Investigators and their staff can download and print a wealth of patient information collected from the CTSU website. Education is essential

to attracting patients, said Ms. Adler. “The physician-investigator has to bridge that gap and provide the right information in language the patient can understand.”

- Investigators are expected to accrue 3 to 5 patients during their first 18 months. “If the investigator has shown dedication to research but for some reason has had a delay and doesn’t have enough patients, all of that will be considered when his renewal comes before the review board,” said Ms. Adler.