The Cancer Trials Support Unit Independent Clinical Research Site: National Cancer Institute's Program to Increase Community Oncologist Clinical Trial Participation

In the late 1990s, the National Cancer Institute (NCI) provided increased opportunities for investigators and patients to participate in NCI-sponsored adult Cancer Cooperative Group (Group) clinical trials through an integrated Web-based support system. The Cancer Trials Support Unit (CTSU) was formed in 1999 to expand access to Cooperative Group phase III cancer treatment trials to all nine adult Group members (see sidebar) and to NCI's

*Andrea Denicoff, RN,
MS, ANP*

Community Clinical Oncology Program (CCOP) including Minority-Based CCOPs. To reach investigators not included in the current NCI-sponsored system, the CTSU developed a new program called the CTSU Independent Clinical Research Site (CICRS) program. CICRS was formally launched at ASCO's 2002 Annual Meeting. "One goal of this program was to include more doctors in clinical trials and to expand trials to places that didn't have as many opportunities

for patients to participate," said Andrea Denicoff, RN, MS, ANP, CICRS contract lead at NCI.

To become a part of CICRS, sites must follow a process similar to any of the Cooperative Group's application processes. Participation through CICRS includes support to sites that help explain institutional review boards (IRBs) and also provides guidance on patient recruitment. Because the CICRS program is designed for smaller sites than the CCOP, it differs from CCOP or Cooperative Group membership in having a lower requirement for patient accrual—five patients per year. These five patients can be accrued to any Cooperative Group trial on the CTSU list, giving sites a lot of freedom. Denicoff said the program's flexibility appeals to many current program members. "Sites have independence to choose whatever trials they want from the CTSU listing," Denicoff said. "They choose trials that both interest them and meet the needs of their patients."

Commonwealth Hematology-Oncology, PC (CHO), located in Concord, Massachusetts, was accepted as a new CICRS site in March 2007 and opened its first trial for accrual in October. CHO has 10 offices and 24 physicians involved in the CICRS program. They see about 7,000 new patients per year, with many from minority populations.

Several offices have had Cooperative Group affiliations in the past, allowing them to participate in Group trials, but CICRS involvement has allowed them to create a unified network within the CHO practice.

Susan Sajer, MD

The increased access provided by the program demands a fairly rigorous process to ensure quality. This includes affiliating with a local IRB, completing regulatory documents, getting proper authorizations, selecting protocols, undergoing audits, and most importantly, recruiting and training research staff. Susan Sajer, MD, of CHO, said training staff is key to successfully launching a clinical trials program.

With 10 sites to coordinate, CHO created a Clinical Research Office to help the staff get accustomed to the new program. The Clinical Research Office Manager holds weekly meetings with office managers, administrative staff, and the CHO president to discuss clinical trials issues. New staff and paperwork creates more financial burden, but for CHO consolidating the 10 offices has actually made their process a little simpler and broadened their trial participation. "This program gives us access to most CTSU adult trials with a reduced administrative burden," Dr Sajer said. "We are able to open a new protocol of our choosing at one or more of our offices within a few weeks."

To help guide their trial selection, her office has developed a clinical feasibility tool. "We quickly realized that some of the more scientifically interesting studies were quite complex and not appropriate for a new research staff," Dr Sajer said. Instead they began with two straightforward studies on breast cancer therapy, National Surgical Adjuvant Breast and Bowel Project (NSABP) B-36 and NSABP B-42, and one more complex study on treatment for metastatic colon cancer, Cancer and Leukemia Group B (CALGB)/Southwest Oncology Group (SWOG) C80405, with plans to expand trials as the staff gets more comfortable with the process.

Other important keys to a successful clinical trials program, she says, are central storage of research-related documents, staff training at all levels, partnership with a local IRB, and local advertisement to encourage participation. The program

has not been without challenges. One of the challenges for CHO has been minority recruitment, given that many trials do not have Spanish language translations of study documents such as patient diaries and calendars. But Dr Sajer sees the benefits of increased protocol availability and access to more trials close to home as outweighing any challenges. Her staff responded to the program with “excitement and enthusiasm,” which will help them grow their clinical trials program.

In developing the CICRS program, one of the main goals was to expand clinical trials offerings to areas that typically would not have access or the infrastructure to meet the Cooperative Group requirements. Five years into the program, the top five accruing sites are in catchment areas of less than 300,000 people. These include sites in Georgia, West Virginia, Virginia, and Kansas. One new site, also in a small catchment area, has quickly launched its clinical trials program in a rural area of North Carolina.

Marian L. Shepherd Cancer Center in Washington, North Carolina, was selected to join CICRS in April 2007 and had accrued four patients by October.

*Jennie Crews, MD,
FACP*

This site is a hospital-based cancer center located in rural eastern North Carolina in a city of about 10,000 people. They have had Cooperative Group affiliation in the past, but chose to apply to CICRS to expand their options. “Previously our participation in trials has come through affiliations with university medical centers in the state,” said Jennie Crews, MD, FACP. “CICRS gives us flexibility to open a broader range of trials tailored to

the needs of our patients. We also have expanded the disciplines represented.”

The Shepherd Cancer Center has two full-time oncologists, five nurses, a nurse practitioner, and two clinical trials nurses to support the program. Clinical Trials Nurse, Cindy Edwards said, “We are thrilled to be part of CICRS and have enjoyed having more control over the selection and conduct of trials at our center.” Sharon Bell, another clinical trials nurse, said that after enrolling a couple of patients, the process became more streamlined and comfortable.

The Shepherd Center also had to overcome the financial burden associated with clinical trials. “We had concerns about enrolling enough patients to offset the costs of using a central IRB, but the variety of studies offered has allowed us to enroll enough patients to compensate for the administrative cost,” Bell said.

Dr Crews hopes that providing more access to trials will encourage patients in the community to participate. She is seeing an increased need for oncology care in the area because of an influx of retirees. Previously, many patients would have had to travel hours to a larger medical center for cancer care. But now, her site has the ability to open trials that serve the center’s patient populations.

Joginder Singh, MD

Although starting a clinical trials program requires a lot of staff up front, the process does get easier over time, said Joginder Singh, MD, of Cedar Valley Medical Specialists. After 2 years of being involved in CICRS, this site in Waterloo, Iowa, is the top accruing site in the program, with nearly 70 patients as of the 2007 ASCO Annual Meeting. Dr Singh has seen positive staff and physician response as well as

positive impacts on patient care.

“Becoming a CICRS site was one of the best things we could have done for our research,” said Dr Singh. “We have been able to participate in an expanded number of studies and are able to give our patients more options when it comes to their care.”

Dr Singh’s office is a growing practice with three physicians and one research coordinator, as well as nurses, laboratory technicians, and other office staff. They see about 100 patients per day. Through CICRS, Dr Singh said they are able to put more patients in studies, providing them with more choices for patient care. The practice has many trials open, but colon and breast cancer studies have had the highest accrual. Patients in the community are also interested in participating in clinical trials, Dr Singh said. “They can be part of cutting-edge research.”

To help sites adjust to increased administrative and financial burdens, NCI offers a mentor to CICRS participants. According to Jenny Hopkins, RN, BSN, of Westat, the company that oversees the NCI contracts, the mentor serves as a one-on-one liaison who works mostly with research staff. Early on, the mentor walks sites through the program, explaining the Web site, how to download protocols, IRB submissions, and describing how to work with the CTSU regulatory office.

“The mentor really walks sites through these things because if you’re not familiar with the CTSU, it can feel like you’re in a foreign land,” Hopkins said. Time spent on these steps and the amount of paperwork involved for CTSU trials is similar to that of other Cooperative Group trials. Participating sites must also meet the accrual requirement of five patients per

year to remain in the program, and they are audited in the same manner as Cooperative Groups. Because offices gain this experience, CICRS can also act as a sort of training ground for those interested in Cooperative Group membership in addition to expanding trial options to their communities.

A few years ago, Exeter Hospital was a member of CALGB through an affiliate network that included New Hampshire Oncology-Hematology, PA, located nearby. The hospital lacked the infrastructure to meet the patient accrual requirements, and CALGB dropped it from the affiliate network until it could develop the resources to meet the Group's requirements. Exeter Hospital then joined the CICRS program, which allowed its staff to participate in CTSU trials.

Denis Hammond, MD, who participated in CICRS, said the program "is a great asset in terms of accruing to clinical trials. It allows for accruals by institutions or practices that might not have the wherewithal to belong to a Cooperative Group." Exeter Hospital participated in CTSU trials as it worked to

meet the CALGB requirements and demonstrate that the site could accrue patients to clinical research protocols. Eventually, the hospital rejoined CALGB as an affiliate of the physician practice, New Hampshire Oncology-Hematology, PA.

So far, the CICRS program has proved to be a great way to expand clinical trial offerings to community physicians and patients who previously may not have had much access to Group trials. Sites perceive the program as being more accessible than membership in a traditional Cooperative Group because the accrual requirements are less burdensome, thus allowing offices with smaller staffs the chance to participate. As the program continues, NCI is exploring ways to offer Web-based training and teleconferences or Webcasts to keep these sites connected—a type of virtual meeting similar to the regular meetings Cooperative Groups hold.

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These NCI-sponsored Cooperative Groups list their trials and participate in the CTSU: American College of Surgeons Oncology Group (ACOSOG), CALGB, National Cancer Institute of Canada Clinical Trials Group (NCIC CTG), Eastern Cooperative Oncology Group (ECOG), NSABP, Gynecologic Oncology Group (GOG), Radiation Therapy Oncology Group (RTOG), North Central Cancer Treatment Group (NCCTG), and SWOG (more information about the CTSU and CICRS is available at: <https://www.ctsuo.org>).

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