

## A Partnership Between the Academic and the Community

David P. Ryan, MD

The relationship between the academic cancer center and the community cancer center is undergoing a dramatic cultural change. Community hospitals across the Northeast are building fully functional cancer centers where they provide all the services necessary for cancer care. Community hospitals tell us that they are increasingly interested in hiring oncologists to serve as salaried employees in a hospital-based ambulatory division rather than hiring private practice oncology groups to staff the clinics, and are looking to become comprehensive in scope. Concurrently, academic medical centers are dealing with the dramatic changes in cancer treatment to more targeted approaches both in the standard of care and in the design and conduct of clinical trials. These cultural changes have created head-scratching moments when community and academic medical centers come together and the community center asks for access to clinical research. At the heart of the confusion is miscommunication between 2 teams regarding what is meant when a community cancer center asks for clinical research in an era of complex and genotype-directed trials.

### The Essential Contract Between Patient and Physician

The physician-patient relationship remains the key building block of *any* cancer center. When a patient and oncologist sit down to decide on a course of action, only 3 treatment decisions are possible at any point: 1) no active treatment (“watchful waiting” or “best supportive care”), 2) standard therapy, or 3) participation in a clinical trial. For a patient to receive the best chance in the best-case scenario, the physician must understand the natural history of the patient’s cancer. The physician must know all the available standard interventions, including surgery, radiation, and medical management, and their impact on the natural history. The physician must also have a working knowledge of the cutting-edge research in the field. With this knowledge, physicians can discuss the options with patients and help patients and families determine the best course. The essential contract is that each oncologist will help each patient have the best chance at the best-case scenario. This contract drives community cancer centers to ask for access to clinical research. However, community cancer centers can already participate in large phase II/III clinical trials through the cooperative group mechanism or through direct contracting with the pharmaceutical industry. So, what are they really asking?

When I get a call or e-mail from a community oncologist to “run a case” by me or see if their patient is a candidate for a trial, we discuss the 3 basic options (discussed earlier) in the course of our conversation. We review the 3 elements in the essential contract because there is no way for me to answer the question about clinical trials without referencing the 3 basic options. With the explosion of knowledge over the past decade, it is nearly impossible for the community oncologist to have an intimate understanding of all 3 options for all patients with cancer seen in a day. When community cancer center executives ask me for access to our clinical trials, they seem to be referring to the trials themselves as though they are pieces of hardware in which their program is deficient. When community oncologists ask for access to clinical research, they are asking for both hardware and software. They are asking for access to complete *the essential contract* with the patient.



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## Changes in Clinical Research

When I first started my career in academic oncology in 1997, the first trial that I led was a phase I study of gemcitabine and docetaxel in patients with solid tumors. This trial led to a phase II study in 35 patients with metastatic pancreatic cancer. Either of these studies could have been safely and effectively conducted in a community site. However, this type of study is becoming increasingly rare because pharmaceutical companies cannot afford them. Today, fellows and young attendings are running trials with titles such as *Phase I Study of a PI3K Inhibitor in PI3K Mutant Patients as Second-Line Therapy in Advanced Solid Tumors*. These studies are multi-institutional and get amended to add expansion cohorts of 15 patients with PI3K mutant breast or colon cancer, and then get amended a second time for an expansion cohort of patients with PI3K mutant breast cancer with documented amplification of the pathway requiring biopsies before and after therapy.

With the identification of multiple targets (eg, ALK, MET, PI3K, BRAF, and more) in multiple cancers, our center has seen an explosion in phase I trials; we expect to enroll more than 300 patients in phase I clinical trials this year. Moreover, pharmaceutical companies are increasingly going straight from phase I studies with expansion cohorts to randomized phase II/III studies, bypassing the simple phase II design.

For community sites to participate in these phase I studies, they must genotype or assess amplified pathways in their patients in a timely fashion. The studies require expertise in nursing and research management and extra chair time to accommodate pharmaceutical sampling. These studies often have complex pharmacodynamic end points, requiring expertise and space for processing and storing samples. Moreover, they need physician expertise to know that this trial is appropriate for the patient sitting in front of them, thus fulfilling *the essential contract*. Even if the community physician was an expert in this pathway and cancer type, they would need to participate in the weekly study phone conferences to go over the emerging toxicities and difficulties with the trial.

Finally, the funding of clinical research is complex. At the Massachusetts General Hospital Cancer Center, our funding typically follows the rule of 3: a third of the funding for clinical research comes from the pharmaceutical industry; a third comes from grants; and a third comes from philanthropy or hospital support. Because cooperative group studies are often run at a loss, hospital and philanthropic support is necessary to continue participation. Community cancer centers with successful participation in cooperative group studies have accepted these extra costs. In addition, a byzantine and unforgiving regulatory environment increasingly stresses the finances of our clinical research portfolio. So when administrators in a community cancer center ask for clinical trials, administrators in the academic cancer center often misunderstand and respond, “Really? You really want *this*?”

## Possible Solutions

An important initial step in any relationship between community and academic cancer centers is a meeting of the executive and physician leadership in the same room. Miscommunications between executive and physician leadership must be resolved for real partnership to occur. When we meet with representatives from community cancer centers and they ask for participation in clinical research, we now dig deeper into their true needs. Community cancer centers have access to phase III studies through the CTSU (Cancer Trials Support Unit) mechanism. We can provide expertise setting up the clinical research structure necessary to conduct these studies. The community sites quickly learn that these studies are prohibitively expensive and then try to assess whether access to these phase III trials is worth the cost.

## Partnerships Between Cancer Centers

When the community sites assess the cost of participation, we arrive at the fundamental questions of supporting the essential contract between the patient and physician. We have several programs that can support the community cancer center in this endeavor. We offer “on-site second opinion clinics” in which one of the oncologists in our disease center will visit the community site and conduct an afternoon of second opinions in a particular disease. This visit allows for better communication between community and academic oncologists and provides community oncologists an opportunity to update their knowledge of the latest advances in the field and the exciting clinical trials that are available. We offer rapid access to second opinions and clinical trials in which we see patients within 1 week of referral. We offer technologic solutions that allow referring doctors to view their patients’ electronic medical records. We offer genotyping to our affiliates so that they can appropriately classify their patients with solid tumors. We are also experimenting with novel ideas such as on-site phase I consults in which a team member from our Center for Targeted Therapies conducts bimonthly consults at the community cancer center for patients considering phase I studies. Finally, we are experimenting with technologic solutions used in other specialties, such as “tele-stroke,” in which community physicians can use computer platforms to rapidly review patient management.

As the care for patients with cancer becomes increasingly complex, so does the interaction between community and academic cancer centers. To navigate the future successfully in this rapidly evolving world, we must remember one of the essential truths of medicine: it all starts with the patient. If we remember the essential contract between the physician and patient, our solutions to navigating these complex interactions will have a greater likelihood of actually providing the best chance at the best-case scenario to all patients, whether they are treated primarily in the community or in the academic medical center.