The Southwest Oncology Group: New Processes to Coordinate Increasingly Complex Clinical Trials

The Southwest Oncology Group (SWOG), a national, government-funded clinical trial coordinating group, launched a quality assessment project in October 2007 to improve its processes. “To remain competitive in this changing environment,” says Dr Laurence H. Baker, DO, Group Chair of SWOG, “we must adapt and be able to conduct smaller, more complex studies efficiently while producing high-quality data.” The project includes a consultant-driven review in tandem with self-studies of all SWOG systems and processes, as well as development of an imaging network. The project will help to prepare SWOG for its upcoming National Cancer Institute (NCI) competitive review, and beyond that, will support SWOG’s major goal of remaining highly competitive as a cooperative group in a world of increasingly complex clinical trials.

Dr Baker says he expects the quality assessment findings to benefit SWOG in several ways. It will help the group to determine where weaknesses exist; if they do, and to correct them. It will keep the group competitive for new trials on the basis of its reputation for accurate data management. And it may help to restore the public’s faith in clinical trials, which has suffered some damage in the media over the years. “No patient wants to feel like a guinea pig,” Dr Baker says. They want to feel assured that they are entering a trial managed by the best of the best.

When Dr Baker presented the quality assessment proposal to SWOG members, “There was a great deal of enthusiasm and excitement from the group,” Dr Baker says. “I was proud of them. No one has imposed this on us. We’re doing it on our own.” Still, while the review is strictly voluntary, he hopes that it will put an end to the Food and Drug Administration’s (FDA’s) tendency to question the accuracy of cooperative group clinical trial data.

SWOG is taking a three-prong approach to its quality assurance review, according to Dr Baker. The SWOG Statistical Center is conducting a self-assessment of its data management systems; SWOG has hired Dr Joseph Pater, MD, retired director of the National Cancer Institute of Canada Clinical Trials Group (NCIC CTG), as a consultant to review SWOG’s system and processes related to data collection and to make recommendations; and SWOG is working with a Boston-based telecommunications company to implement a SWOG imaging network.

About SWOG

SWOG is one of the largest of the 12 groups in the NCI-supported Cooperative Group Program, which involves more than 1,700 institutions that contribute patients to group-conducted clinical trials. Thousands of individual

investigators participate in NCI-supported cooperative group studies. Cooperative groups place more than 22,000 new patients into cancer treatment clinical trials each year.¹

The cooperative groups differ in structure and research focus. Some groups, such as the Children’s Oncology Group, consist of investigators who have a particular medical specialty (eg, pediatrics); some, such as the Radiation Therapy Oncology Group, study a specific type of cancer therapy; and others, such as the Gynecologic Oncology Group, focus on a group of related cancers. The groups share a common purpose—to develop and conduct large-scale trials in multi-institutional settings.¹

Funded by research grants from the NCI and other sources, SWOG and other cooperative groups conduct clinical trials to prevent and treat cancer and to improve quality of life for cancer survivors. SWOG celebrated its 50th anniversary in 2006. SWOG studies many adult cancer types, including breast, gastrointestinal, genitourinary, gynecologic, and lung cancers, as well as melanoma, myeloma, leukemia, and lymphoma. Approximately 120 clinical trials are under way at any given time.¹ A major focus for SWOG is cancer control and prevention. SWOG has completed accrual of two large studies aimed at preventing prostate cancer. Today, SWOG cancer control activities are centered on cancer survivorship, health disparities, molecular epidemiology, symptom management, and cancer chemoprevention.

The group’s network of more than 5,000 researchers practice at nearly 550 institutions. Among SWOG institutions are 17 of the NCI’s 61 designated cancer centers. Physicians must meet strict medical and ethical requirements to become members of SWOG and to conduct the Group’s protocols. Medical practices represented in the Group include university teaching hospitals, community hospitals, community-based physician cooperatives, and individual physician offices.

More than 7,000 new patients with cancer are enrolled each year in group studies, and approximately 35,000 more are involved annually in ongoing clinical trials. During the last 25 years, more than 170,000 patients have directly benefited from the group’s trials, while millions more have received improved care as the group develops new standards of treatment or prevention.²

Dr Baker became chairman during the spring 2005 SWOG meeting in Denver. Dr Baker joined SWOG in 1972 and served in several capacities, including chairman of the Intergroup Sarcoma Committee and associate Group chairman. On accepting the chairmanship, Dr Baker established the Group Headquarters Office at the

University of Michigan in Ann Arbor, where he is a professor of Internal Medicine and Pharmacology.

Taking a Closer Look at Systems and Processes

Dr Baker hired a well-recognized, national expert when he contracted last summer with Joseph Pater, MD, formerly director of the NCIC CTG. Dr Pater recently retired from the NCIC CTG (April 2007) after 27 years of service. While he still works for the NCIC CTG 1 day a week, he says that he had just begun thinking about what it would be like to put up his feet and take it easy when Dr Baker contacted him. The SWOG Quality Assessment Initiative grabbed his attention immediately. “It was quite interesting to me to look at how another group of investigators do what I’ve been doing for nearly 30 years. I’m finding it personally and intellectually satisfying.”

For his part, Dr Baker saw Dr Pater as perfect for the job, which is to review all of SWOG’s systems and processes and make recommendations. Dr Pater received the Diamond Jubilee Award from the NCIC, one of six awards given on the occasion of NCIC’s 60th anniversary to recognize researchers for contributions to cancer research in Canada. “As director of the NCIC CTG, [Dr] Pater led a group that exceeded the quality standards,” Dr Baker says. “His clinical trials network in Canada serves as a model for other countries around the world.”

Speaking from a conference he was attending in Toronto, Dr Pater said he is conducting his assessment in three phases. The first, which already was well under way when this issue of *JOP* was in production and was expected to last about 2 months, was the fact-finding phase. Dr Pater attended the October 2007 SWOG meeting and talked to people there and then visited the SWOG Operations Office in San Antonio, Texas, and the Statistics Center in Seattle, Washington, where he interviewed the various professionals involved about their systems and processes.

He is looking at SWOG’s processes for data collection, including the mechanics of setting up a trial, writing protocols, creating case reports, collecting the data, quality control of the data, checking the data, and procedures for reporting adverse events. Dr Pater said that the physical set-up of SWOG (being split among three locations) is different from what he is accustomed to, which is a program housed all under one roof. He will be assessing whether that physical set-up itself creates any quality issues. “I am interested in assessing how SWOG integrates the various activities involved in a clinical trial,” says Dr Pater, who will be examining how each of the three SWOG centers operate, how they divide tasks, and whether they’ve adopted the best models for integrating those tasks.

He also has talked to leaders of the US NCI Cancer Therapy Evaluation Program to get a feel for the political climate and

familiarize himself with some of the current issues facing the cooperative groups, like discussion around the FDA’s use of cooperative group data for drug approval and the current state of tight funding for large-scale trials. He also planned to visit other organizations that run cancer and noncancer clinical trials as comparators.

Dr Pater expected the fact-finding phase of his work to finish in November 2007. He planned to meet with Dr Baker at the end of December, kicking off the second phase of his work, which is the recommendation phase. He then planned to attend the SWOG Retreat in February 2008 to report his initial findings; the final phase of his work would culminate when he submits a final report to Dr Baker in March 2008.

SWOG Statistical Center

As Dr Pater does his assessment, the SWOG Statistical Center already is involved in a self-evaluation of its systems and processes. Having recently made the shift from paper to electronic records is a bonus now that accuracy is even more important to monitor than ever. SWOG staff now is checking how that transition from paper to electronic records has gone, what went well and what they could do better. The new system has an edit check function, Dr Baker says, that catches many types of data entry errors instantly. If, for instance, the physician puts in the wrong age for the patient, stating that he was born in 1926 instead of 1962, the electronic system catches the error immediately. An important error like this could have been overlooked for months in a paper system. The Statistical Center staff will be looking at some of the same things that Dr Pater will be studying to see if they are, for instance, collecting the right data, collecting enough data, or perhaps collecting too much.

Launching an Imaging Network: Partnering With AG Mednet

As SWOG assessed its processes and systems, both internally and externally, another key part of the SWOG Quality Assessment was in discussion—development of an imaging network for the secure and Health Insurance Portability and Accountability Act (HIPAA)-compliant efficient transfer of radiologic images used to assess clinical trial patients. For this, the SWOG imaging network is partnering with AG Mednet, which provides what the company describes as the world’s largest diagnostic imaging exchange network (Fig 1).³ “This partnership is providing the opportunity to greatly improve the quality of data by providing the mechanism for a real-time third-party research read of images,” Dr Baker says. “We want the freedom to be able to go anywhere to get the best and most appropriate radiologist to review the films in a given trial,” he says. “This network will allow that.” The first study to use this technology is opening in early 2008 with a myeloma clinical trial comparing the clinical utility of MRI with standard x-rays and will last about 18 months to 2 years. “Other trials will come along,” Dr Baker says. “A couple of the SWOG committees, lung, lymphoma, already were quite enthusiastic. We have more people interested than dollars can

Figure 1. The Southwest Oncology Group (SWOG)/AG Mednet diagnostic imaging exchange network. PACS, picture archival communication system.

support at the moment.” No NCI funding is involved in this trial, according to Dr Baker, who says SWOG is using funds from the SWOG Hope Foundation, member donations, patient donations, and pharmaceutical industry grants.

SWOG anticipates that its imaging network participants should have round-the-clock delivery of secure digital images to trial repositories, should have faster and easier access to expert interpretation, and the project should require no capital investment and minimal training and technology maintenance investment.³

Despite this cutting-edge technology, Dr Baker is a realist and cautions that there will be hurdles. He’s sensitive to HIPAA and other privacy considerations and regulations, as well as the need to be FDA-compliant. “There are important issues,” he says. “We have to demonstrate that no one can interfere or tamper with the images, that we’re being HIPAA-compliant, and that we are cognizant of and protect against the potential for wrongdoing.”

The process for accessing this network includes the development of “agent” sites for high-volume institutions and the ability to download software for institutions that are less active and non-SWOG institutions for “per-study” involvement. The first participating agent sites will be set up in December 2007 through April 2008 at 40 sites. When the myeloma clinical trial gets under way and researchers begin to use the network, additional sites will get instructions as they open. “A goal for the SWOG Imaging Network had to be the minimal impact on workflow,” Dr Baker says. “We recognize our investigators are busy and can’t add to their workload. In many cases, while a new process is initially cumbersome,

ultimately it will decrease the workload, and that is one reason that AG Mednet was an ideal choice for the project.”⁴

Conclusion

The accuracy and integrity of clinical trial data is paramount because increased scrutiny from outside funders demands internal attention to accurate and high quality data. Advances in technology have helped researchers on many fronts. Electronic patient records and electronic image transfer are two such advances. As SWOG immerses itself in reviewing its records, systems, and processes; assessing the success of its transition to electronic medical records; and moves to electronic image transfer, the group becomes an example of best practices. As Dr Baker and so many oncologists say, ultimately, it’s all about improving the lives of the patients.

There’s an expression, “A miss is as good as a mile,” and it is relevant here; there really are no small errors in the clinical trial setting, and vigilant attention to detail and accuracy are essential to creating sound data that protect patient safety and maintain the cooperative group’s reputation of excellence.

Dr Baker said that the cooperative groups are in competition and when a hot new drug comes along, each wants to be the group to test it. “I want SWOG to get it because our data management is good,” Dr Baker says. So, SWOG is taking a proactive approach to its future security as it deals with budget cuts and trying to do more with less. Dr Baker is striving to have the group motivated to find ways to do things better and smarter so that the patient ultimately is the beneficiary.

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