

## **Interacting with Other Cooperative Groups**

The Southwest Oncology Group participates in NCI-sponsored intergroup protocols. These are protocols in which more than one cooperative group participates. The protocol is coordinated by only one of these groups. The three types of participation are as follows.

### **Other Group-Coordinated Protocols Not Conducted Through the Cancer Trials Support Unit**

For non-SWOG intergroup treatment trials that are not conducted through the NCI funded Cancer Trials Support Unit, the Southwest Oncology Group primarily participates by contributing towards the accrual of patients onto the protocol. Currently, the Southwest Oncology Group participates in 15 of these intergroup protocols. The Statistical Center's responsibilities for all of these trials include cooperating with the coordinating group's statistical center and operations office by performing data monitoring and follow-up tasks as required.

Additionally, except for trials coordinated by ECOG, CALGB, or NCCTG, the Statistical Center's responsibilities also include forwarding data to the coordinating group.

For trials coordinated by ECOG, CALGB, and NCCTG, a Direct Data Submission Initiative has been piloted and proven successful for expedient data transfer to the coordinating group. Via this direct data submission initiative, data are submitted by the institution directly to the coordinating group, bypassing the participating group's data operations center. A nightly secure ftp database transfer from the coordinating group to the participating group updates the patient's survival and last contact information as it is processed by the coordinating group.

Except for trials coordinated by ECOG, the Statistical Center is responsible for conducting patient registrations for intergroup/non-CTSU trials. For ECOG coordinated studies, a computer-based project linking the SWOG and ECOG databases for patient randomizations has proven successful, thus eliminating the need for SWOG data coordinators to contact the ECOG randomization office for every SWOG patient registered to an ECOG trial.

For registrations on non-CTSU protocols managed by another cooperative group besides ECOG, a data coordinator contacts the other cooperative group statistical center and obtains treatment assignment and patient identification numbers. The data coordinator is then responsible for completing the registration by calling the Southwest Oncology Group clinical research associate and relaying the treatment assignment and patient identifying information as indicated by the protocol.

The Statistical Center facilitates its participation in non-CTSU intergroup protocols managed by other groups by recording in the Southwest Oncology Group database the patient number assigned to Southwest Oncology Group patients by other groups. Follow-up information for non-SWOG studies is included in the expectation report and IPR calculations as a performance factor.

## **Other Group-Coordinated Trials Conducted Through the Cancer Trials Support Unit**

The Statistical Center's responsibilities for non-SWOG trials conducted through the Cancer Trials Support Unit differ in that patient enrollment and data submission is routed from institution to CTSU to coordinating group. In addition, the CTSU is responsible for cooperating with the coordinating group's statistical center and operations offices by routing data and follow-up requests as required. Registration information is relayed to the SWOG Statistical Center for recording (for those CTSU studies endorsed by SWOG).

## **Southwest Oncology Group-Coordinated Protocols**

Currently, the Southwest Oncology Group coordinates 15 open intergroup treatment protocols. These studies are available to non-SWOG participants either via the CTSU menu, or directly with specific cooperative groups. For these protocols, a number of innovations have been implemented.

1. The computerized registration system is programmed to recognize intergroup protocols. When the registering institution is from another group, the program follows special instructions with respect to identification of the registering investigator and institution, dynamically balanced treatment assignment, the expectation list, and specific notes directed to the registering groups.
2. The Southwest Oncology Group Statistical Center has designed its investigator roster and the follow-up information in the database to be able to identify the investigator and institution associated with each patient in requests for follow-up data sent to other statistical centers.
3. The expectation reports and requests for follow-up sent to other group statistical centers are specifically designed to facilitate communication with their institutions, and are therefore different in style and content from the analogous reports sent to institutions in the Southwest Oncology Group.
4. The Southwest Oncology Group has made on-line registration available to institutions of two of its intergroup partners (ECOG and ACoSOG), and is developing similar links to other cooperative groups.
5. The Southwest Oncology Group Statistical Center data coordinators and biostatisticians have available to them special reports designed to facilitate the monitoring of intergroup studies. These reports are for monitoring accrual (by group) and identifying data submission or follow-up problems.
6. The Southwest Oncology Group is developing procedures to allow participation with collaborators from Europe and Asia.